IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., and INCEPT LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 15-819-LPS-CJB
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently before the Court is Plaintiffs Integra LifeSciences Corp. ("Integra LSC"), Integra LifeSciences Sales LLC ("Integra LSS"), Confluent Surgical, Inc. ("Confluent") (collectively, "Integra") and Incept LLC's ("Incept") (with Integra, collectively referred to herein as "Plaintiffs") Motion for Preliminary Injunction (the "Motion"). (D.I. 8) Plaintiffs seek to enjoin Defendant HyperBranch Medical Technology, Inc. ("HyperBranch" or "Defendant") from commercially using, selling, and offering for sale within the United States HyperBranch's allegedly infringing dural sealant products. (D.I. 121 at 1; D.I. 122, Second Declaration of Karen L. Pascale (hereinafter, "Second Pascale Decl."), ex. 1) For the reasons set out below, the Court recommends that Plaintiffs' Motion be DENIED.

I. BACKGROUND

A. Factual Background

1. Dural Sealants Generally

Neurosurgical procedures frequently involve either deliberate or unintended durotomies, which are breaches of the thick membrane surrounding the brain and spinal cord known as the dura. (D.I. 10, Declaration of Karen L. Pascale (hereinafter, "First Pascale Decl."), ex. 3 at ¶ 7; *id.*, ex. 4 at ¶ 34) Each year in the United States, there are approximately 420,000 neurosurgical procedures involving a dural defect or durotomy. (*Id.*, ex. 3 at ¶ 7; *id.*, ex. 4 at ¶ 40) During these procedures, closure of the dura is achieved through the use of various combinations of sutures, collagen matrices, autografts and synthetic grafts. (*Id.*, ex. 3 at ¶ 7; *id.*, ex. 4 at ¶ 34) Dural sealants can be used as a supplement to these methods to enhance the closure. (*Id.*, ex. 3 at ¶ 7; *id.*, ex. 4 at ¶ 34) By some estimates, dural sealants are used in more than one third of the dural defect or durotomy repairs that occur each year. (*Id.*, ex. 3 at ¶ 7; *id.*, ex. 4 at ¶ 40) Dural sealants help to prevent the leakage of cerebrospinal fluid ("CSF") from the closures, and they can also reduce potential adverse effects such as infections. (*Id.*, ex. 3 at ¶ 7; *id.*, ex. 4 at ¶ 35)

2. Plaintiffs

Integra LSC is the corporate parent and sole owner of its subsidiaries Integra LSS and Confluent. (*Id.*, ex. 3 at ¶ 3) Integra manufactures and distributes Integra products, including the Integra DuraSeal® ("DuraSeal") and DuraGen® ("DuraGen") product lines. (*Id.*) Integra LSC is involved in the design, development and manufacturing of medical devices for orthopedics, tissue technologies and speciality surgical solutions, with an emphasis on products that help heal and/or regenerate tissue. (*Id.* at ¶ 4) Integra LSS sells and distributes Integra's medical technology products, including Integra's dural sealant products, worldwide. (*Id.*) Confluent is a medical device company that has engaged in the development of in-situ polymerized biomaterials with applications as synthetic sealants and hemostats in minimally invasive surgery, adhesion

prevention and interventional procedures. (*Id.*)

Incept is a medical technology company that promotes and advances technological innovation and entrepreneurship. (*Id.* at ¶ 5) Incept was (as was Confluent) founded by Dr. Amarpeet Sawhney. (D.I. 35, ex. 1 at ¶ 1; D.I. 94 at 4; Tr. at 227)

a. Asserted Patents

Incept is the owner of U.S. Patent Nos. 6,566,406 (the "'406 patent"), 7,009,034 (the "'034 patent"), 7,332,566 (the "'566 patent"), 7,592,418 (the "'418 patent"), 8,003,705 (the "'3705 patent") and 8,535,705 (the "'5705 patent") (collectively, the "patents-in-suit" or "asserted patents"). (D.I. 1 at ¶¶ 11-16) Confluent is the exclusive licensee of the asserted patents. (First Pascale Decl., ex. 3 at ¶ 8)

Integra LSC acquired Confluent on January 15, 2014 from Confluent's prior owner, Covidien LP ("Covidien"). (*Id.*; *see also* D.I. 78 at 1)[1] At the time of this acquisition, Confluent's most important assets were the DuraSeal® product line (a product line described more fully below) and its exclusive licenses for the patented inventions. (First Pascale Decl., ex. 3 at ¶ 8)

The asserted patents, in turn, are necessary in order to make, use and sell certain Integra products, including those that are part of the DuraSeal product line. (*Id.* at ¶ 5) The patents all come from the same patent family and are directed to biocompatible crosslinked polymers (i.e., hydrogels) having certain features and methods for their preparation and use. (*Id.*, exs. 5-10)

The '418 patent is a continuation of the '556 patent, which is a continuation of the '034

[1] Sometime after this acquisition, Covidien was acquired by Medtronic, Inc. (D.I. 77 at 1; D.I. 78 at 1)

patent. It is entitled "Biocompatible Crosslinked Polymers with Visualization Agents" and it issued with 30 claims. (*Id.*, ex. 5) The '556 patent has the same title and issued with 38 claims. (*Id.*, ex. 6) The '034 patent is entitled "Biocompatible Crosslinked Polymers" and issued with 22 claims. (*Id.*, ex. 7) These three patents are directed to the following technological area:

> Biocompatible crosslinked polymers, and methods for their preparation and use, are disclosed in which the biocompatible crosslinked polymers are formed from water soluble precursors having electrophilic and nucleophilic functional groups capable of reacting and crosslinking in situ. Methods for making the resulting biocompatible crosslinked polymers biodegradable or not are provided, as are methods for controlling the rate of degradation. The crosslinking reactions may be carried out in situ on organs or tissues or outside the body. Applications for such biocompatible crosslinked polymers and their precursors include controlled delivery of drugs, prevention of post-operative adhesions, coating of medical devices such as vascular grafts, wound dressings and surgical sealants. Visualization agents may be included with the crosslinked polymers.

(*Id.*, exs. 5-7, Abstracts)

The '406 Patent is also entitled "Biocompatible Crosslinked Polymers" and issued with 27 claims. (*Id.*, ex. 8) The '406 patent is directed to the same general technological area as the '418, '556, and '304 patents, but does not discuss visualization agents. (*Id.*, Abstract) The '3705 patent is entitled "Biocompatible Hydrogels Made with Small Molecule Precursors" and issued with 22 claims. (*Id.*, ex. 9) The '3705 patent is directed to the same general technological area as the '418, '556 and '304 patents, but also discusses hydrogel embodiments having isolated hydrolytically degradable esters and embodiments using low molecular weight amines to make the hydrogels. (*Id.*, Abstract) The '5705 patent is entitled "Biocompatible Polymers and Hydrogels and Methods of Use" and issued with 18 claims. (*Id.*, ex. 10) Its Abstract is nearly

identical to the Abstracts of the '418, '556 and '304 patents set out above, but it does not discuss visualization agents, and it notes that the precursors have electrophilic and nucleophilic groups (but not electrophilic and nucleophilic *functional* groups). (*Id.*, Abstract)

b. Plaintiffs' Dural Sealant Products

Integra's DuraSeal product line includes two products: (1) the DuraSeal Dural Sealant (hereinafter, "DuraSeal"), which is a dural sealant that prevents leakage of CSF after cranial procedures, and which was the only such sealant approved by the United States Food and Drug Administration ("FDA") in the United States from April 2005 until 2015; and (2) DuraSeal Exact Spine Sealant, which has been the only FDA-approved dural sealant for spinal uses in the United States since its approval in September 2009. (*Id.*, ex. 3 at ¶¶ 6, 8; *id.*, ex. 4 at ¶ 20) A representative picture of DuraSeal is shown below:

(*Id.*, ex. 3 at ¶ 6)

DuraSeal is comprised of a two-component system wherein the two components mix as they exit the applicator to form a hydrogel. (*Id.*) The first hydrogel component is a polyethylene glycol ("PEG") ester with a phosphate buffer, and the second hydrogel component is a trilysine amine with a borate buffer. (*Id.*) Synthetic colorants (such as to form a blue color) are added to the second component to allow visualization of the product application. (*Id.*) Once applied to the dural closure, the hydrogel is absorbed by the body over a 4 to 8 week period. (*Id.*)

Currently, fibrin glues are used as dural sealants for durotomies more often than is

DuraSeal. (*Id.* at ¶ 7) Even though such use of fibrin glues is off-label, it is common because fibrin glues are generally on the surgical cart and readily available to surgeons. (*Id.*)

3. Defendant and its Products

Defendant HyperBranch is a specialty medical device company that was founded in North Carolina in 2003. (D.I. 95, Declaration of Jeffrey G. Clark (hereinafter, "Clark Decl."), at ¶ 4; *About Us*, HyperBranch.com, http://www.hyperbranch.com/us/About.html (last visited Aug. 8, 2016) (*cited in* D.I. 94 at 2)) HyperBranch currently employs 13 people, and the company has always operated out of its headquarters in Durham, North Carolina. (Clark Decl. at ¶¶ 4, 6) HyperBranch designs, develops, manufactures and sells medical products for adhering and sealing tissues. (D.I. 37 at ¶ 19; *see also About Us*, HyperBranch.com, http://www.hyperbranch.com /us/ About.html (last visited Aug. 8, 2016) (*cited in* D.I. 94 at 2))

Currently, HyperBranch sells only two products: the accused Adherus AutoSpray Dural Sealant (the "AutoSpray product") and Adherus Dural Sealant (the "non-AutoSpray product")[2] (collectively, the "Accused Products" or "Adherus"). (Clark Decl. at ¶¶ 11, 16, 18; D.I. 94 at 2)[3] The Accused Products are comprised of two components, a PEG component and a polyethyleneimine ("PEI") polymer component. (D.I. 97, Declaration of Dr. Anthony Lowman

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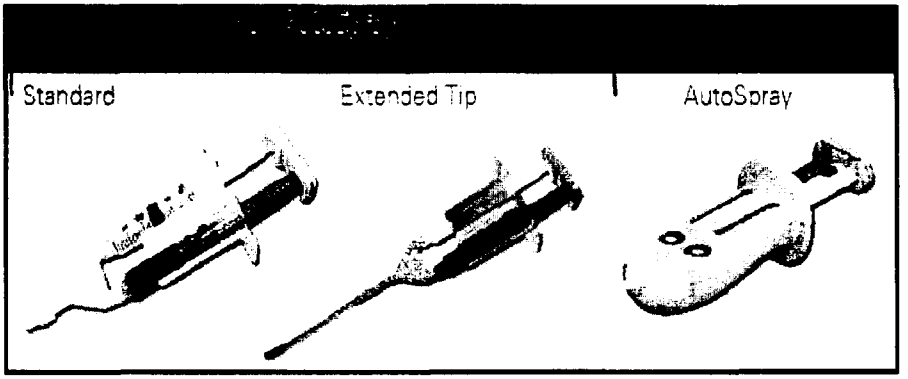
[2] Originally named "NuSeal 100," HyperBranch renamed the non-Autospray product as Adherus Dural Sealant in March 2010. (Clark Decl. at ¶ 10) Nothing else about the product changed other than its name. (*Id.*)

[3] Although Plaintiffs seek to enjoin HyperBranch from commercially using, selling, and offering for sale within the United States HyperBranch's AutoSpray product and non-Autospray product as well as its Adherus Spinal Sealant, (*see* Second Pascale Decl., ex. 1), HyperBranch no longer manufacturers or sells Adherus Spinal Sealant, (Clark Decl. at ¶ 16). The final lot of that product was produced in September 2013, and HyperBranch shipped the last of the final lot in May 2014. (*Id.*).

("Lowman Decl."), at ¶ 35) The products are sold in packages containing a vial of the PEG ester component and a green colorant dye, a vial of the PEI component, and a dual-barrel applicator with pre-loaded buffer solutions. (*Id.*) The chemical structure of the two components of the AutoSpray product and non-AutoSpray products are the same, but the products have different applicators. (*Id.*) While the non-AutoSpray product uses a traditional hand-powered dual barrel syringe system, the AutoSpray product has a powered air-assist feature that utilizes pressurized air to spray the materials. (*Id.*) The different applicators for the Accused Products are depicted below:



(*Id.*)

After exiting the applicators of the Accused Products, the delivered solution immediately crosslinks to form a hydrogel that is absorbed by the body over approximately 90 days. (First Pascale Decl., ex. 13 at ex. C at 4 & ex. D at 2) The AutoSpray and non-AutoSpray products are intended for use "as an adjunct to standard methods of dural repair, such as sutures, to provide a watertight closure during cranial procedures." (Lowman Decl. at ¶ 37 (internal quotation marks and citation omitted))

HyperBranch's first sale of an Accused Product was for the non-AutoSpray product and it

occurred in May 2009 in South Africa. (Clark Decl. at ¶ 11) Two months later, in July 2009, HyperBranch received a CE Mark for its non-AutoSpray product. (*Id.* at ¶ 12) A CE Mark connotes regulatory approval to sell a medical device in Europe, and such products require a label that includes the product manufacturer's name and address. (D.I. 102, Declaration of Adam M. Pivovar ("First Pivovar Decl."), ex. F at 55; Clark Decl. at ¶¶ 13-14) Thus, since at least 2009, the product label for the non-AutoSpray product has identified HyperBranch and its North Carolina address. (First Pivovar Decl., ex. G; Clark Decl. at ¶ 14) HyperBranch received a CE Mark for the AutoSpray product in May 2012, and its product label has identified HyperBranch and its North Carolina address since at least that time. (Clark Decl. at ¶¶ 12, 14) Outside the United States, HyperBranch's Accused Products compete with several other products, including DuraSeal. (*Id.* at ¶ 22)

Following FDA-approved studies that began in 2009 and 2010, respectively, HyperBranch received FDA approval to sell the AutoSpray product in the United States in March 2015. (*Id.* at ¶¶ 17-18) On or about July 23, 2015, HyperBranch made its first sale of the AutoSpray product to its distributors in the United States. (*Id.*; *see also* Plaintiffs' Preliminary Injunction Presentation, Slide 5) HyperBranch's distributors are responsible for selling the products directly to end customers. (Clark Decl. at ¶ 24) The AutoSpray product is the only HyperBranch product that has received FDA approval for sale in the United States and, relatedly, is the only HyperBranch product that has been sold in the United States. (*Id.* at ¶ 18)

4. Plaintiffs' Knowledge of Defendant's Products

In the fall of 2007—several years before its acquisition of Confluent—Integra contemplated a possible acquisition of HyperBranch. (First Pivovar Decl., ex. A; Clark Decl. at ¶

5) In this timeframe, certain Integra employees circulated an Executive Summary that described HyperBranch's business; they also signed a Non-Disclosure Agreement provided by HyperBranch and thereafter reviewed and distributed HyperBranch's Confidential Offering Memo. (First Pivovar Decl., ex. A; Clark Decl. at ¶ 5) HyperBranch's Executive Summary disclosed that it was a North Carolina company currently developing three products: the non-AutoSpray product (then known as NuSeal 100), a sealant for use in ocular surgery and a sealant for use in pulmonary surgery. (First Pivovar Decl., ex. B) Integra e-mails discussing the possible acquisition further described HyperBranch's then-named-NuSeal 100 product as a "biocompatible" product that was "designed with low swelling characteristics" and with "degradation characteristics specifically tuned to match the healing times of the treated tissue." (*Id.*, ex. A at INT00220209; *see also id.*, ex. B)

In January 2008, Dr. Sawhney (Confluent's and Incept's founder) sent a letter to HyperBranch's North Carolina headquarters. The letter identified HyperBranch's ocular sealant as potentially infringing certain patents owned by Incept, including the '406 patent. (*Id.*, ex. C)[4]

There is record evidence that by 2009, employees of both Integra and of Confluent's then-owner, Covidien, were aware of HyperBranch's CE Mark. In July 2009, an Integra Vice President of Program Management and Clinical Affairs sent an e-mail to Integra business development personnel that attached a HyperBranch press release; the press release, in turn, discussed HyperBranch's receipt of the CE Mark. (*Id*, ex. D) In 2009, Covidien employee Jason Fortier (an employee who went on to have further dealings with HyperBranch's products) was aware that the

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[4] The '406 patent (as noted above) is asserted in this litigation, but none of its claims are among those Plaintiffs have focused on for purposes of the instant Motion.

non-AutoSpray product was being sold in Europe and had obtained a CE Mark. (*Id.*, ex. F at 55)

Later in 2009, Covidien employees obtained samples of HyperBranch's NuSeal 100 sealant for testing "to see how it worked and what it looked like" and to see how it compared to DuraSeal. (*Id.*, ex. F at 20-23, 189-190; *id.*, ex. H) One of the purposes of this testing was also to determine whether the NuSeal 100 product infringed, *inter alia*, the asserted patents. (*Id.*, ex. V at 94-96) During the first half of 2010, Covidien employees performed the testing at the direction of Covidien in-house intellectual property ("IP") counsel Kevin Ferguson. (*Id.*, ex. F at 22, 38-39, 68-69) More specifically, Covidien employees functionally tested the product samples to see how quickly the product reacted, how much it swelled, how long it lasted in a simulated *in vivo* environment, and to gauge the product's burst strength. (*Id.* at 22-23) Covidien also commissioned a lab to perform a chemistry evaluation of the product. (*Id.* at 22)

From August 2009 through April 2013, Covidien documents and e-mail communications reflect the company's awareness that HyperBranch was gearing up to launch in the United States a dural sealant with an "improved applicator" intended to address the "main complaint" of DuraSeal users, who were reporting problems with DuraSeal's delivery system. (*See, e.g.*, D.I. 151, Declaration of Adam M. Pivovar ("Second Pivovar Decl."), exs. FF-LL) For example, Covidien employees knew about HyperBranch's United States pilot study for its dural sealant in August 2009; during the following year, they discussed HyperBranch's "pivotal study" in the United States that would utilize DuraSeal as the "control" group. (*Id.*, exs. FF-GG) During the fall of 2012, Covidien employees continued to track HyperBranch's trial sites and FDA-approval progress. (*Id.*, exs. JJ, NN) In 2013, Covidien conducted analyses of the effect of HyperBranch's trials on purchasing decisions and revenue, as well as analyses of HyperBranch's U.S. market

entry strategy. (*Id.*, exs. OO, PP) And throughout this 2009-2013 timeframe, as they were monitoring HyperBranch's progress, Covidien employees continued to exchange numerous e-mail communications in which they discussed problems associated with DuraSeal—including problems with the product's "delivery system," a perceived "increased . . . infection rate," leakage and adhesion issues and swelling issues. (*See, e.g., id.*, exs. FF, HH, KK, MM)

[redacted] (D.I. 144, ex. DD at 39-45) In January 2015, a year after the acquisition, Integra sent a letter to HyperBranch, in which it stated that it was aware that HyperBranch "is making, marketing, and/or selling surgical sealants outside the United States, and is seeking FDA approval for its [AutoSpray product] in the United States." (*Id.*, ex. EE) The letter attached copies of the asserted patents (as well as two additional patents not at issue in this litigation) and explained that "Integra greatly values its intellectual property rights, and, accordingly is identifying those rights for [HyperBranch's] review with respect to HyperBranch's activity regarding surgical sealants." (*Id.*)

B. Procedural Background

On September 15, 2015, Plaintiffs brought the present action, alleging that HyperBranch infringes the asserted patents. (D.I. 1) That same day, Plaintiffs also filed the instant Motion. (D.I. 8)

On September 25, 2015, Chief Judge Leonard P. Stark referred this case to the Court to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive

motions. (D.I. 15) Soon thereafter, the Court set a schedule for briefing on the Motion and for limited discovery relating to the Motion; that schedule ordered Plaintiffs to identify a total of six claims that would be at issue in the preliminary injunction proceedings. (D.I. 28) Plaintiffs thereafter selected the six claims at issue for purposes of this Motion: claim 14 from the '034 patent, claims 9 and 31 from the '566 patent, claim 25 from the '418 patent, claim 6 from the '3705 patent and claim 17 from the '5705 patent. (D.I. 135, ex. B)

Following the parties' exchange of discovery during a contentious discovery process[5] and after the completion of briefing, (D.I. 9, 94, 121, 144, 150), the Court heard oral argument on Plaintiffs' Motion on April 26, 2016, (D.I. 159 (hereinafter, "Tr.")).[6] The parties thereafter submitted supplemental letters attaching documents and evidence that were referenced during the oral argument, but that were not included within the briefing record. (D.I. 152, 153)

II. STANDARD OF REVIEW

"[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993); *accord Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 996 (Fed. Cir. 1985) ("Only a viable threat of

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[5] The Court heard and ruled upon several discovery disputes that arose between the parties during the limited discovery period. (*See, e.g.*, D.I. 74, 86, 112) Certain of those disputes related to HyperBranch's request for an order compelling Plaintiffs to obtain and produce documents in their control that were in the possession of Covidien's current owner, Medtronic. (*See* D.I. 77, 87) The Court ultimately granted that request, (D.I. 84), and also permitted HyperBranch to submit a supplemental brief to address the impact of the Covidien/Medtronic document production, (D.I. 150).

[6] Prior to oral argument, the parties also each filed motions seeking to strike certain materials and arguments relating to the Motion (the "motions to strike"). (D.I. 132, 134) Pursuant to a request from HyperBranch, the Court issued a ruling in advance of the oral argument, which granted the first component of HyperBranch's motion to strike. (D.I. 148) The Court will issue its rulings on the remainder of the motions to strike below.

serious harm which cannot be undone authorizes exercise of a court's equitable power to enjoin before the merits are fully determined.") (internal quotation marks and citations omitted). However, the Patent Act provides that injunctions "may" issue "in accordance with the principles of equity[.]" 35 U.S.C. § 283.

A movant for a preliminary injunction pursuant to 35 U.S.C. § 283 must establish: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). No one of these factors is dispositive; "rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Id.* (quoting *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988)). However, "a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm." *Id.* (emphasis in original). Moreover, "[w]hile granting a preliminary injunction requires analysis of all four factors, [] a trial court may . . . deny a motion based on a patentee's failure to show *any* one of the four factors—especially either of the first two—without analyzing the others." *Jack Guttman, Inc. v. KopyKake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002) (emphasis added); *see also Chrysler Motors Corp. v. Auto Body Panels of Ohio, Inc.*, 908 F.2d 951, 953 (Fed. Cir. 1990) ("If the injunction is denied, the absence of an adequate showing with regard to any one factor may be sufficient, given the weight or lack of it assigned the other factors, to justify the denial.").

III. DISCUSSION

A. Likelihood of Success

With regard to the first factor, Plaintiffs must show that, in light of the presumptions and burdens that will inhere at trial on the merits: (1) HyperBranch likely infringes at least one of the claims of the asserted patents; and (2) the infringed claim(s) will likely withstand HyperBranch's challenge to validity. *Amazon.com, Inc.*, 239 F.3d at 1350. Analysis of HyperBranch's alleged infringement requires a two-step process: (1) "the district court must determine the scope of the patent claims," and then must (2) "determine whether properly interpreted claims encompass the accused structure." *Hybritech Inc.*, 849 F.2d at 1455.

The Court has determined that it will not substantively address this first factor. Instead, it will assume *arguendo* that Plaintiffs could prove a likelihood of success on the merits, and go on to assess the remainder of the factors below. It takes this path for a few reasons.

It does so first because, at this stage of the litigation, the key liability issues are not always well fleshed out in the record. In part, that is because: (1) the patents relate to complex subject matter; (2) the parties did not request increased page limits for briefing on the Motion; and (3) Plaintiffs did not narrow the asserted claims down to the six presently at issue until after they had filed their opening brief. In light of this, the parties ended up with a limited number of pages of briefing in which to take on a large and complicated set of liability-related issues, as well as all of the other issues that are relevant to the question of whether to enter a preliminary injunction. Moreover, the parties did not propose claim constructions for relevant claim limitations, and this further complicated the process of assessing the merits of infringement and invalidity issues. (*See, e.g.*, Tr. at 151-54, 192-96) The net effect of all of this was that, at times, the parties' briefing regarding the "likelihood of success" factor was cursory. And so the Court is not in as strong a position as it might be to adjudge the relative merit of all of the relevant claims and

defenses.

The Court also proceeds in this fashion because, in the end, it is legally unnecessary to do otherwise. In light of the Court's conclusion below that Plaintiffs have not sufficiently demonstrated that irreparable harm will befall them in the absence of the requested relief, no injunction could issue. And so, an assessment of Plaintiffs' likelihood of success on the merits is not required for purposes of resolving the Motion. *See, e.g.*, *Chestnut Hill Sound Inc. v. Apple Inc.*, Civil Action No. 15-261-RGA, 2015 WL 6870037, at *2 (D. Del. Nov. 6, 2015) (taking this same approach under similar circumstances); *Depuy Synthes Prods., LLC v. Globus Med., Inc.*, C.A. No. 11-652-LPS, 2013 WL 4509655, at *2 (D. Del. Aug. 22, 2013) (finding that the plaintiff failed to establish irreparable harm and that therefore it was unnecessary to address the remaining preliminary injunction factors).

B. Irreparable Harm

It is well established that a party seeking a preliminary injunction "must make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and immediate irreparable injury." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("*Apple II*") (internal quotation marks and citation omitted); *Chestnut Hill Sound Inc.*, 2015 WL 6870037, at *3. To demonstrate irreparable harm, a plaintiff must establish that it is subject to harm that can not be adequately compensated though monetary damages. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) ("[T]he irreparable harm inquiry seeks to measure harms that no damages payment, however great, could address."). A plaintiff satisfying the irreparable harm factor must also demonstrate a causal nexus relating the alleged harm to the alleged infringement. *Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 678 F.3d 1314,

1324 (Fed. Cir. 2012) ("*Apple I*"); *Chestnut Hill Sound Inc.*, 2015 WL 6870037, at *3.

HyperBranch's attack on Plaintiffs' showing as to the irreparable harm factor is multi-pronged. HyperBranch argues that: (1) Plaintiffs' delay in seeking injunctive relief precludes a finding of irreparable harm; (2) any alleged harm to Plaintiffs is not immediate and is purely speculative; (3) any such harm will be adequately compensated with money damages; and (4) Plaintiffs failed to demonstrate a sufficient nexus between the alleged harm and HyperBranch's alleged infringement. (D.I. 94 at 6-10; *see also* D.I. 144 at 1-3 & n.1; D.I. 150) The Court will consider each of these arguments in turn.

1. Delay

HyperBranch first asserts that Plaintiffs unduly delayed in bringing this infringement action and in seeking injunctive relief. This delay, according to HyperBranch, demonstrates that Plaintiffs will not really suffer irreparable harm if the Motion is denied. (D.I. 94 at 6-7; D.I. 144 at 1-2; D.I. 150 at 4-5)

A showing of delay does not preclude a determination of irreparable harm as a matter of law; rather, it is "but one circumstance that the district court must consider in the context of the totality of the circumstances." *Hybritech Inc.*, 849 F.2d at 1457. And yet, the United States Court of Appeals for the Federal Circuit has made clear that delay is "an important factor bearing on the need for a preliminary injunction." *High Tech. Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (citations omitted); *see also Apple I*, 678 F.3d at 1325 ("[D]elay in bringing an infringement action and seeking a preliminary injunction are factors that could suggest that the patentee is not irreparably harmed by the infringement."); *Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991) (explaining that delaying "for a substantial

period of time before seeking a preliminary inunction *at least suggests that the status quo does not irreparably damage*" the patentee) (emphasis added). While a showing of delay does not preclude, *as a matter of law*, a determination of irreparable harm, if the delay is significant enough, a district court could, in its discretion, find that delay alone demonstrates that the patentee cannot show irreparable harm. *Hybritech Inc.*, 849 F.2d at 1457.

In assessing the question of whether and how long Plaintiffs delayed in filing the Motion, the Court must first clarify what kind of conduct is it that—if known to Plaintiffs—should be said to have started the "delay clock" running in earnest. Initially in this case, Plaintiffs sought a preliminary injunction with respect to a broad scope of allegedly infringing activities undertaken by HyperBranch. At that time, Plaintiffs were requesting an order enjoining HyperBranch "from commercially making, using, selling, or offering for sale within the United States and exporting from the United States" the Accused Products. (First Pascale Decl., ex. 1) Had the Plaintiffs not later narrowed the focus of their request for preliminary relief "to enjoin only HyperBranch's *sales of products in the U.S.*[,]" (D.I. 121 at 1 (emphasis added)), there would be no real question that Plaintiffs had engaged in prolonged delay in filing suit here (at a minimum, with regard to the apparatus claims at issue). That is because, as will be discussed further below, Plaintiffs have known for a very long time about HyperBranch's U.S.-based *manufacture* of allegedly infringing products for *sale to overseas entities*.

However, Plaintiffs have now framed their claim of irreparable harm more narrowly. That is, they are now asserting only that *the U.S.-based sale* of HyperBranch's Accused Products (that is, the sale of products in the United States to customers in the United States) is what threatens it with irreparable harm. In light of this more narrowly-framed articulation of the irreparable harm

at issue, the Court agrees that the proper focus of the "delay" inquiry should be on Plaintiffs' delay in seeking injunctive relief from the date of their knowledge of HyperBranch's U.S.-based sales activity.[7] (*See* Tr. at 15-16, 19-20, 22-23 (Plaintiffs' counsel explaining that the delay analysis focuses on "when did the irreparable harm begin. And that began with U.S. sales. The U.S. market and the foreign market are very, very different market[s]. There's like 10 different competitors in the foreign market . . . . [W]ith [the AutoSpray product] being approved in March of 2015, [the United States market] became a two[-]supplier market, [and that] completely changed the dynamics of the market and resulted in what we see now as being this irreparable harm to the Plaintiffs."); Clark Decl. at ¶ 22 (listing nine foreign competitors of the Accused Products)); *cf. Neology, Inc. v. Fed. Signal Corp.*, C.A. No. 11-672-LPS/MPT, 2012 WL 2308202, at *17 (D. Del. June 18, 2012) (assessing the length of a patentee's delay in bringing a preliminary injunction motion from the time in which the patentee knew that it had first lost a sale to the accused infringer in the United States, and also from a later time period when the patentee first learned of the details associated with that lost sale, in a case where the patentee asserted that the magnitude of its lost U.S. sales to the accused infringer triggered irreparable harm); *Power Integrations, Inc. v. BCD Semiconductor Corp.*, Civ. No. 07-633-JJF-LPS, 2008 WL 5069784, at *12 (D. Del. Nov. 19, 2008) (timing the extent of the patentee's delay in bringing a preliminary

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[7] The Court is somewhat sympathetic to HyperBranch's charge that "[a]fter HyperBranch spent a significant amount of money [rebutting] Plaintiffs' arguments for an injunction against all sales and manufacturing in the U.S.—effectively a worldwide ban on sales of the Accused Products—Plaintiffs sandbagged HyperBranch by moving the target" and narrowing their injunction request to simply U.S.-based sales. (D.I. 135 at 1 n.1) But on the other hand, that narrowing of Plaintiffs' argument was at least of some benefit to HyperBranch too, in that it eliminated any possibility of an injunction as to global sales of the Accused Products.

injunction motion from, at its furthest point, the date on which the patentee first lost sales to the accused infringer). This seems logical, as if a patentee is arguing that an accused infringer should be enjoined because a particular kind of infringing act is causing it irreparable harm, then the patentee would not seem to be properly motivated to seek an injunction until the infringer actually started to (or was about to) commit that particular infringing act. *Cf. EcoNova Inc. v. DPS Utah*, No. 1:12-CV-174-TC, 2012 WL 5944257, at *2, *14 (D. Utah Nov. 28, 2012) (rejecting the defendant's argument that the plaintiff's delay of at least 9 months before seeking injunctive relief prevented a finding of irreparable harm, where the plaintiff knew about and monitored the defendant's activities relating to the accused products for months before filing the motion for preliminary injunction, because the plaintiff "adequately explained the reasons for the purported delay"—during that timeframe, plaintiff was not aware of any actual sales or leases of defendant's product, and when plaintiff learned that defendants were quickly moving to sell an actual product, thus transforming from "an entity interfering with [plaintiff's] patent rights into a competitor selling infringing technology[,]" it filed for injunctive relief).

With that as prelude, the Court assesses whether any appreciable delay occurred here. Plaintiffs claim that "there was no delay" since HyperBranch made its first sale of the AutoSpray product on July 23, 2015, and Plaintiffs filed the instant Motion on September 15, 2015—a bit less than two months later. (D.I. 121 at 1; Tr. at 15-16) For the reasons set forth below, the Court finds that Plaintiffs' actions—in the context of this particular record—at most amount to only a slight delay in bringing the Motion.

a. Evidence pre-dating Defendant's first U.S.-based sale

As noted above, the Court agrees with Plaintiffs' position that the amount of the delay at

issue here should be timed from Plaintiffs' knowledge of the particular infringing activity that Plaintiffs assert gave rise to the alleged irreparable harm—the U.S.-based sales of the Accused Products. With that said, however, the Court does not agree with Plaintiffs that any evidence demonstrating their earlier knowledge of the Accused Products and of other allegedly infringing activity is *irrelevant* to the question of delay. Instead, the entire context matters. It stands to reason, for example, that if a plaintiff has known about an assertedly infringing product for many years—and then later becomes aware of particular infringing activity as to that product that is said to cause it irreparable harm—that a plaintiff should be much more prepared (as compared to one who just learned of the offending product's existence) to take quick action to stop the infringement. And here, the four Plaintiffs at issue knew about HyperBranch's Accused Products, and knew or should have known about the alleged infringement as to those products, for quite a while prior to the start of U.S. sales of the AutoSpray product.

The Court will first assess Confluent's knowledge in this regard. As summarized above in Section I.A.4. and as set out in HyperBranch's briefing, Confluent's prior owner, Covidien, was aware for years of: (1) HyperBranch, (2) the Accused Products and (3) the manufacture of the Accused Products in the United States. To summarize, briefly:

> (1) By June 2009, Covidien received notice that HyperBranch had obtained a CE Mark to sell the non-AutoSpray product in Europe.;
>
> (2) Later in 2009, Covidien obtained samples of that product for testing, to compare it to DuraSeal.;
>
> (3) During the first half of 2010, Covidien employees tested the non-AutoSpray product, at the direction of Covidien's in-house counsel, and commissioned a lab to perform a chemistry evaluation of the product. This testing was done both for commercial purposes and to evaluate potential patent infringement by HyperBranch.; and

> (4) From August 2009 through April 2013, Covidien employees repeatedly discussed HyperBranch's planned launch of the AutoSpray product in the United States, tracked the progress of HyperBranch's studies of this product and of the FDA approval process for the product, discussed the fact that the product was intended to address certain perceived deficiencies in Covidien's DuraSeal product, and conducted analyses of the effect of HyperBranch's product on customer purchasing decisions and revenue. These communications, which are numerous and are very detailed in their discussion of the AutoSpray product, are outlined at greater length in Section I.A.4.

In light of this evidence, the Court easily concludes that as of at least mid-2010, Covidien knew or reasonably should have known of HyperBranch's alleged infringement activities—i.e., making certain of the Accused Products in the United States. 35 U.S.C. § 271(a); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) (in considering the question of delay regarding a plaintiff's showing of irreparable harm, considering whether the defendant demonstrated that the plaintiff "knew or should have known" about certain plans leading to the allegedly infringing activity); *cf. Arcsoft, Inc. v. Cyberlink Corp.*, 153 F. Supp. 3d 1057, 1075 n.11 (N.D. Cal. 2015) (in a trademark infringement action, in discussing whether delay undercut the plaintiff's claim of irreparable harm, noting that the plaintiff "knew or should have known of defendants' use of the Infringing Marks long before July 2015").

The Court also agrees with HyperBranch that Covidien's knowledge may be imputed to Confluent (the exclusive licensee of the patents) in these circumstances. Although Confluent was Covidien's wholly owned subsidiary from late 2009 through 2014, and even though Confluent may not technically have employed anyone in that time, (Tr. at 16-17; Plaintiffs' Preliminary Injunction Presentation, Slide 6 (citing D.I. 88, ex. 3 at 183-84)), the evidence reflects that certain Covidien employees devoted significant time to Confluent-related work—some "[f]ull-[t]ime"

and others "[p]art-time[,]" (D.I. 152, ex. B; D.I. 91, ex. 1). These employees included, for example, Mr. Fortier, who was involved with Covidien's 2010 comparison testing of the non-AutoSpray product and DuraSeal. (*See, e.g.*, First Pivovar Decl., ex. F at 20-23; *id.*, ex. H) It also includes William Delaney, Frederic Le Roy and David Chisholm, who during various points from 2009-2013 monitored HyperBranch's FDA approval process and discussed the development of an applicator similar to the AutoSpray product's applicator. (*See, e.g.*, Second Pivovar Decl., exs. FF-JJ, NN) This evidence indicates that (1) even if these persons were technically considered "Covidien" employees during this timeframe, in a very practical sense, they were also "Confluent" employees too; and (2) they had knowledge of the matters at issue due to their Confluent-related work. (D.I. 150 at 4 n.2); *cf. McRO, Inc. v. Namco Bandai Games Am., Inc.*, 23 F. Supp. 3d 1113, 1125 (C.D. Cal. 2013) (explaining that in willful infringement context, "knowledge of a patent by a parent corporation is not necessarily imputed to the subsidiary" but can be if there is evidence that would support imputing such knowledge); *Semiconductor Energy Lab. Co. Ltd. v. Chi Mei Optoelectronics Corp.*, 531 F. Supp. 2d 1084, 1114-15 (N.D. Cal. 2007) (same, with regard to a motion for summary judgment regarding damages). The record here supports imputation of such knowledge to Confluent. *Cf. Afros S.P.A. v. Krauss-Maffei Corp.*, 671 F. Supp. 1458, 1459-60 (D. Del. 1987) (concluding that the willfulness of the parent corporation could be imputed to its wholly owned subsidiary where the evidence demonstrated that, *inter alia*, a number of executives played significant roles in both companies).

As for the other Integra Plaintiffs, they too were aware for years of HyperBranch's existence, of the Accused Products, and of the fact that those products were being manufactured

and developed in North Carolina.[8] What follows is a summary of this evidence from the year 2007 to the beginning of 2015:

> (1) In the fall of 2007, Integra contemplated an acquisition of HyperBranch. In assessing whether the acquisition made sense, Integra reviewed HyperBranch information showing that the non-AutoSpray product was being made in North Carolina, and Integra employees discussed and analyzed that product in e-mail correspondence.
>
> (2) In July 2009, Integra employees, including Integra's Vice President of Program Management and Clinical Affairs, shared e-mail correspondence attaching a HyperBranch press release that discussed HyperBranch's receipt of the CE Mark.

[redacted][9]

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[8] Plaintiffs have not suggested that the knowledge of Integra LSC and Integra LSS differs at all for purposes of this analysis.

[9] The Court also finds that, based on the record before it, all of Confluent/Covidien's prior knowledge of HyperBranch and the Accused Products should be attributed to Integra, due to Integra's purchase of Confluent. In a number of cases in which other equitable remedies were at issue, a predecessor's knowledge and its actions (or inaction) have been attributed to subsequent acquirers for purposes of considering whether the acquirer delayed in filing suit. *See, e.g.*, *High Point SARL v. Sprint Nextel Corp.*, 67 F. Supp. 3d 1294, 1306-07 (D. Kan. 2014) (resolving a motion for summary judgment on the grounds of laches and estoppel, and finding that the plaintiff "is both bound by the actions (and inaction) of its predecessors-in-interest and imputed with their knowledge" and that "[i]t is especially true that a prior patent owner's delay in filing suit is attributed to subsequent patent owners") (citing cases); *TQP Dev., LLC v. Intuit Inc.*, CASE NO. 2:12-CV-180-WCB, 2014 WL 2809841, at *8 (E.D. Tex. June 20, 2014) (explaining that in the laches context, "[t]he period of delay in bringing suit begins at the time the patentee or his predecessor in interest has actual or constructive knowledge of the defendant's potentially infringing activities") (internal quotation marks and citations omitted); *I/P Engine, Inc. v. AOL Inc.*, 915 F. Supp. 2d 736, 743 (E.D. Va. 2012) (noting that in the laches context, "it is settled law in the United States that in determining the length of delay, a transferee of the patent must accept the consequences of the dilatory conduct of immediate and remote

> (4) In January 2015, Integra sent a letter to HyperBranch (attaching copies of, *inter alia*, the asserted patents), which stated that Integra was aware that HyperBranch was manufacturing, marketing and selling surgical sealants outside the United States, and that HyperBranch was seeking FDA approval for the AutoSpray product in the United States. The letter suggested that HyperBranch review the asserted patents with regard to HyperBranch's activity as to surgical sealants.

Thus, at a minimum, by early 2015, Integra had some rights in the asserted patents, and was thoroughly familiar with HyperBranch and the fact that the company was poised to be in a position to sell the AutoSpray product in the United States.[10]

From there, it is not disputed that when HyperBranch received FDA approval in March 2015 to sell the AutoSpray product in the United States, the Integra Plaintiffs were very much aware of that fact.[11]

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transferors") (internal quotation marks and citation omitted).

[10] As to Incept, it too knew—or should have known—of the prospect of infringement by HyperBranch's products by at least several months before the AutoSpray product's July 2015 launch. Incept's founder, Dr. Sawhney, has been directly involved, on Incept's behalf, in past communications with HyperBranch regarding infringement of Incept's patents (including an asserted patent). In January 2008, Dr. Sawhney sent a letter to HyperBranch's North Carolina headquarters identifying a HyperBranch's ocular sealant product (not an Accused Product in this matter) as potentially infringing certain patents owned by Incept—including one of the patents asserted in this case. Moreover, there is evidence that as of March 2014, Dr. Sawhney was discussing the AutoSpray product with Integra employees, as part of a broader discussion of the DuraSeal portfolio. (First Pivovar Decl., ex. K) And of course, by January 2015, Integra was sending copies of the Incept asserted patents to HyperBranch for its review, (D.I. 144, ex. EE); one can fairly infer that Incept was then aware of that activity.

[11] HyperBranch notes that after this March 2015 FDA approval, "Integra still did not sue and seek an injunction"—"[i]nstead, Integra waited further while HyperBranch geared up for the U.S. launch, including by developing a network of distributors and taking initial product orders." (D.I. 144 at 1-2) Plaintiffs respond by asserting that activities undertaken to obtain FDA approval are not actionable under patent law, and therefore that the date of FDA approval could not be a trigger regarding delay—that delay instead must be measured from the first United States sale of an Accused Product. (Tr. at 16; Plaintiffs' Preliminary Injunction Presentation,

b. Assessing delay in light of Defendant's first U.S.-based sale

HyperBranch launched the AutoSpray product on or about July 23, 2015, and it is not disputed that Plaintiffs were aware of this on or about the launch date. After that, HyperBranch notes that "[s]till, Integra took no action until September 2015, 19 months after its acquisition of Confluent, 8 months after its letter to HyperBranch about the patents, and 6 months after FDA approval." (D.I. 144 at 2) The instant suit was ultimately brought on September 15, 2015, just shy of two months after the date of the first United States sale.

In a typical case, filing suit less than two months from the date of an event said to cause one irreparable harm would not appear to suggest any delay at all. It takes time to carefully draft and prepare the large number of documents that accompanied the Motion and the Complaint in this case, to say nothing of the time necessary for the internal client discussions that would necessarily precede such filings.

On the other hand, as of July 23, 2015, these Plaintiffs—to a degree greater than most—had long-standing knowledge of: (1) the AutoSpray product; (2) the product's alleged infringement of the asserted patents; and (3) the product's imminent sale in this country. (*See, e.g.*, D.I. 144, exs. DD, EE; Tr. at 217-18) As a result, it seems hard to conceive of Plaintiffs who would have been more prepared to file suit as of the date of the first U.S. sale of the AutoSpray product than these Plaintiffs were. Equipped with all of this knowledge, it does seem that if Plaintiffs faced truly irreparable harm from the sale of that product, they might have moved a bit

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Slide 5 (citing 35 U.S.C. § 271(e)(1); *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989)). Again, for its purposes here, the Court is noting Integra's knowledge of the FDA approval process not because it necessarily starts the "delay clock" running, but because it provides additional context for how well-familiar Plaintiffs were about possible infringement by the AutoSpray product at the time HyperBranch's United States-based sales commenced.

faster than they did.

In the Court's view, the right way to account for these particular facts is to conclude that there was at most a slight delay in filing suit here, as compared to what might have been reasonably expected. In light of the relatively small amount of time that passed between the first U.S. sale of an Accused Product and the Motion's filing, the "delay" factor should not have a significant impact on an assessment of irreparable harm. *Cf. Hologic, Inc. v. Minerva Surgical, Inc.*, Civ. No. 15-1031-SLR, 2016 WL 3143824, at *10 (D. Del. June 2, 2016) (finding the delay factor to be "neutral" in a case where the plaintiff "had some notice and knowledge of" the accused product after it investigated acquiring the defendant in 2011-12, the FDA approved the accused product in August 2015, the plaintiff obtained the accused device in September 2015 in order to conduct an infringement analysis, the plaintiff filed the lawsuit in November 2015, and it moved for a preliminary injunction in December 2015; the Court found that the timing of suit appeared to "strategically coincide[] with the launch and starting sales of [the accused product]"); *Adobe Sys. Inc. v. Kornrumpf*, No. C 10-2769 CW, 2011 WL 6303358, at *3 (N.D. Cal. Dec. 16, 2011) (finding, in a copyright case, that a "relatively short delay" of two and a half to three and a half months between the plaintiff's knowledge of continuing infringing activity and the filing of its motion "weighs slightly against a finding of irreparable harm").

2. Harm

Plaintiffs argue (and HyperBranch disputes) that in the absence of the requested relief, Plaintiffs will suffer irreparable harm in various forms. Plaintiffs assert that such harm will come to its DuraSeal product line in the form of: (1) loss of market share; (2) loss of growth opportunities; (3) price erosion; (4) loss of synergy with other Integra products; and (5) potential

negative reputational effects to hydrogel sealants generally. (D.I. 9 at 16-19) As discussed more fully below, the Court finds that Plaintiffs have not established than any of its fears as to these types of harm amount to a sufficient showing of irreparable harm at this juncture.

a. Loss of market share

One way a patentee could be harmed through infringement is by losing market share to the accused infringer. But if loss of market share is to be a factor at all in the irreparable harm calculus, it is well-settled that the "lost market share must be proven (or at least substantiated with some evidence) in order for it to support entry of a preliminary injunction, because granting preliminary injunctions on the basis of speculative loss of market share would result in granting preliminary injunctions in every patent case where the patentee practices the invention." *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 301 (Fed. Cir. 2009) (internal quotation marks and citation omitted)).[12]

In their opening brief, filed on September 15, 2015, Plaintiffs claimed that the imminent harm they faced in this regard would soon materialize. They argued then that HyperBranch's infringement would deprive them of their right to exclusive manufacture and sale of the patented products, which would in turn result in "*immediate* loss of business to Integra including a loss of market share and market opportunities in the United States." (D.I. 9 at 16 (emphasis added)) In

[12] Even if the party moving for a preliminary injunction establishes that it has lost market share to an alleged infringer, that fact alone cannot be sufficient to establish irreparable harm. *See, e.g.*, *Pruvit Ventures, Inc. v. Forevergreen Int'l LLC*, CIVIL ACTION NO. 4:15-CV-571-ALM-CAN, 2015 WL 9876952, at *6 (E.D. Tex. Dec. 23, 2015) (citing cases); *Arthrex, Inc. v. dj Orthopedics LLC*, No. CIV.A. 02-67 GMS, 2002 WL 818062, at *4 (D. Del. Apr. 30, 2002). Since lost sales revenue is generally compensable through damages, evidence of such losses is insufficient by itself to demonstrate irreparable harm. *See, e.g.*, *Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, 708 F. Supp. 2d 527, 532 (D. Md. 2010).

support, Plaintiffs relied upon the declaration of their damages expert, John Jarosz, and upon the declaration of Integra LSC's Global Director for Marketing for the Special Surgical Solutions division, Curtis Lenox. (D.I. 9 at 16-17 (citing First Pascale Decl., ex. 3 at ¶¶ 10-11, ex. 4 at ¶¶ 67-79))

Yet Plaintiffs' claims were not born out. As of January 22, 2016—four months after Plaintiffs' opening brief was filed—Mr. Lenox acknowledged that he did "not [then] have proof or knowledge of any lost business." (First Pivovar Decl., ex. E at 22) And two and a half months after that, when Plaintiffs filed their reply brief in April 2016, the record was hardly much different. (D.I. 121 at 8-9)

Instead, at the time of the filing of their reply brief, Plaintiffs provided (via Mr. Lenox) a new explanation as to why any real loss of market share had not yet come to pass. Mr. Lenox now claimed that, in light of sales activity by HyperBranch distributors over the prior two months, there would soon be "a veritable flood of . . . lost business between two and six months from now." (Second Pascale Decl., ex. 21 at ¶ 6) But he asserted that such harm had not yet materialized because of the lengthy "multi-step process" that hospitals utilize before purchasing new products like the AutoSpray product. (*Id.*) In attempting to demonstrate the harm soon to come, Mr. Lenox, along with Mr. Jarosz, noted only that as of April 2016, there were a few hospitals that were now utilizing the AutoSpray product. (*Id.*, ex. 21 at ¶ 5; *id.*, ex. 22 at ¶ 25) More specifically, Mr. Jarosz explained that "there are [redacted] hospitals in the U.S. that are currently stocking accused Adherus products," though he did note that "the Adherus products are under review in 'approximately [redacted] other hospitals." (*Id.*, ex. 22 at ¶ 20 (citing Deposition of Jeffrey Clark, March 25, 2016, at 66-67); *see also* Tr. at 103 (Plaintiffs' counsel explaining that

"HyperBranch's progression through typical hospitals[']' new product procedures has . . . started to result in significant U.S. sales of Adherus. Around at least 200 actual lost sales of DuraSeal in at least 12 of Integra's top 200 hospitals"))

Therefore, the Court agrees with HyperBranch that "either the harm [claimed by Plaintiffs was feared to be] immediate and irreparable in September 2015 [but] has failed to materialize, or the harm was neither immediate nor irreparable in the first place." (D.I. 144 at 2-3) And HyperBranch is also right to say that Plaintiffs have not yet been able to persuasively "point the Court to . . . [any] loss of market share." (*Id.* at 2; D.I. 121 at 8 (Plaintiffs asserting in their reply brief that due to expected future events the "value of [Integra's] exclusivity" in the dural sealant area "will *soon* be irretrievably lost") (emphasis added)) Indeed, seven months after the Motion was filed, Plaintiffs can point to scarcely any lost sales at all, and have made no assertion that the amount of AutoSpray product sales in the [redacted] hospitals referenced above have made any appreciable dent in DuraSeal's market share. *Johnson & Johnson Orthopaedics, Inc. v. Minn. Mining & Mfg. Co.*, 715 F. Supp. 110, 112 (D. Del. 1989) (explaining that "'irreparable injury' is pregnant with meaning. The harm must be imminent, [] not otherwise compensable by money damages, [] actual, [] and sufficiently peculiar []. The moving party must make a clear showing of immediate irreparable injury or a presently existing actual threat, but an injunction will not issue merely to assuage the fears of the movant.") (certain internal quotation marks and citations omitted).

The Court does acknowledge that there is reason to believe that Integra will suffer some greater amount of lost sales to HyperBranch at some point in the future, were the requested relief not granted. After all, the parties are direct competitors in the dural sealant market—and, in fact,

are the only two FDA-approved suppliers in that market.[13] (D.I. 144 at 3 (HyperBranch acknowledging that "some direct competition is inevitable")) Moreover, Plaintiffs have pointed to three pieces of evidence indicating that HyperBranch is actively targeting at least some users of DuraSeal:

> (1) As Plaintiffs' damages expert notes, "it appears that the majority of the distributors selected by Hyper[B]ranch to sell Adherus products are former distributors of DuraSeal products." (Second Pascale Decl., ex. 22 at ¶ 26)
>
> (2) Plaintiffs cite to one HyperBranch document—an "Adherus Sales Strategy" presentation—as further evidence of targeting. (D.I. 121 at 8 (citing Second Pascale Decl., ex. 20 at HBMT0010877)) This presentation instructed distributors that sales of the AutoSpray product [redacted] (Second Pascale Decl., ex. 20 at HBMT0010877; *see also id.*, ex. 22 at ¶¶ 22, 26)
>
> (3) Plaintiffs proffer the supplemental declaration of Mr. Lenox, wherein he states that "[s]ome 46% of Integra's top 200 largest DuraSeal accounts have been approached by Adherus AutoSpray Dural Sealant distributors in the last two months" and that "[m]ore than 25% of these same top DuraSeal customers have received formal product demonstrations, and nearly half of these top DuraSeal customers have completed a trial, are now trialing, or have agreed to trial Adherus AutoSpray Dural Sealant at their facilities." (*Id.*, ex. 21 at ¶ 4)

Yet this evidence does not alter the Court's ultimate conclusion here. Even if the Court could presume that Plaintiffs will lose some amount of sales to HyperBranch in the dural sealant market going forward, the state of the record does not allow it to presume that a substantial loss of market share is likely to happen anytime soon. To that end, it is also important to note that the

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[13] There are of course other alternatives to dural sealants for neurosurgeons to choose from, with fibrin glue "compris[ing] the majority of the U.S. market for dural closures." (D.I. 144 at 3 (citing First Pivovar Decl., ex. E at 64); *see also* First Pascale Decl., ex. 3 at ¶ 7)

record demonstrates a huge disparity in revenues from sales of DuraSeal versus revenues from sales of HyperBranch's Accused Products. While U.S. sales of DuraSeal totaled over [redacted] in 2014, (First Pascale Decl., ex. 4 at ¶ 14), HyperBranch's U.S. sales as of February 2016 totaled [redacted], (Clark Decl. at ¶ 31; *see also* D.I. 96, Declaration of Douglas Kidder ("Kidder Decl."), at ¶ 28 (noting that at the end of 2015, the AutoSpray product "had a negligible share of the U.S. market with total sales to distributors of [redacted] and an unknown amount of those products sold by distributors into the market")). "Given this large disparity in revenue, it is highly unlikely that [HyperBranch] will cause substantial and irreparable harm to [Plaintiffs'] much larger market share" in the foreseeable future. *Arthrex Inc. v. dj Orthopedics LLC*, No. CIV.A. 02-67 GMS, 2002 WL 818062, at *4 (D. Del. Apr. 30, 2002) (finding no irreparable harm where the plaintiff's revenue was over 300 times as large as the defendant's revenue); *see also Conair Corp. v. Barbar, Inc.*, No. 6:14-cv-831-Orl-31TBS, 2014 WL 2993724, at *1-2 (M.D. Fla. July 3, 2014) (finding no irreparable harm where the products appeared similar but "there was a striking difference in the volume of sales between the Plaintiffs' product and the Defendants' product[,]" where Defendants' total sales represented .025% of Plaintiffs' projected sales for the current year).

In sum, due to the extremely limited evidence of any actual lost sales, and due to the overall state of the record, Plaintiffs' market share-related arguments do not support a finding of irreparable harm. *Cf. Techradium, Inc. v. Blackboard Connect Inc.*, Civil Action No. 2-08-CV-00214-TJW, 2009 WL 1152985, at *2 & n.1, *7 (E.D. Tex. Apr. 29, 2009) (finding that the patentee would not suffer irreparable harm where it pointed to at least two examples of lost sales to the accused infringer, as the patentee's "conceived harm is not such that it could not be

adequately remedied by an award of money, should [the patentee] be ultimately successful at trial").

b. Loss of growth opportunities

Next, Plaintiffs assert that in the absence of a preliminary injunction, they will suffer from irreparable harm to their "[g]rowth [o]pportunities[.]" (First Pascale Decl., ex. 4 at 23; *id.* at ¶¶ 67-78; D.I. 9 at 16-17) This argument has two strains, but neither are particularly compelling.

First, Plaintiffs assert that if an injunction does not issue, Integra will be forced to divert resources from their current focus of touting DuraSeal's benefits [redacted], and instead will have to focus on defending their existing business against the "anticipated lower cost" AutoSpray product. (D.I. 9 at 16-17 (citing First Pascale Decl., ex. 3 at ¶ 11; ex. 4 at ¶¶ 67-72)) But this argument suffers from multiple defects. For example, as will be discussed below with regard to Plaintiffs' price erosion argument, the evidence does not actually bear out that the AutoSpray product will be priced substantially lower than DuraSeal. (*See, e.g.*, Clark Decl. at ¶ 25; Kidder Decl. at ¶¶ 25, 27) Additionally, Plaintiffs have not actually altered their growth strategy to date—despite the fact that, according to Plaintiffs, HyperBranch has [redacted] had its Adherus products either stocked in or under review by approximately [redacted] as of early 2016. (Second Pascale Decl., ex. 22 at ¶¶ 20, 23; *id.*, ex. 21 at ¶¶ 4-5) Indeed, four months after Plaintiffs set out this "loss of growth" argument in their opening brief, Mr. Lenox testified that Integra's "growth" strategy still remained "focus[ed]" on [redacted]

[redacted]

Plaintiffs' second argument here is that HyperBranch's U.S. market entry "would prematurely limit or potentially halt customer loyalty that Integra could obtain for the DuraSeal product line, for being the only dural sealant on the market (i.e., Integra's 'first mover advantage')." (D.I. 9 at 17 (citing First Pascale Decl., ex. 4 at ¶¶ 73-79)) Of course, as the use of the word "potentially" above highlights, this argument carries with it a hefty element of speculation, since there is hardly any actual record of lost sales (and thus, lost customer loyalty) to HyperBranch. Moreover, as Mr. Kidder points out on HyperBranch's behalf, although Integra acquired the DuraSeal product line in 2014, the line "has been sold in the U.S. for over ten years[.]" (Kidder Decl. at ¶ 65) Thus, in light of this 10-year head start over any other player in this market, it seems somewhat difficult for Plaintiffs to argue that "DuraSeal is in . . . [imminent] danger of losing a first-mover advantage." (*Id.*)

For these reasons, the Court does not give Plaintiffs' "loss of growth" arguments great weight.

c. Price erosion

Plaintiffs next claim that the AutoSpray product's entry into the market "will also likely cause Integra to suffer price erosion for its DuraSeal products[.]" (D.I. 9 at 17) Here Plaintiffs rely in significant part on Mr. Lenox's declaration for the proposition that, when it comes to sales overseas, HyperBranch has offered its dural sealant products at a "substantially reduced (e.g., 20-30%) price as compared to" the price of DuraSeal. (First Pascale Decl., ex. 3 at ¶¶ 10-11) Mr. Lenox suggested in his declaration that HyperBranch will likely do the same with its AutoSpray product in the United States. (*Id.*; *see also id.*, ex. 4 at ¶ 79 (Mr. Jarosz stating that "[*i*]*f* similar

price competition were to occur in the U.S., Integra would be forced to lower its DuraSeal prices to retain existing business and to obtain new business") (emphasis added)) Plaintiffs' price erosion theory is also based on the assumption that "Adherus is expected to compete with DuraSeal by entering contracts with Group Purchasing Organizations ['GPOs']" [redacted] [14] (*Id.*, ex. 4 at ¶¶ 81-82) For at least the following four reasons, however, the Court concludes that these tenets of Plaintiffs' price erosion theory stand on very shaky evidentiary ground.

First, there is no real support in the record for the claim that HyperBranch has, in fact, actually charged a "substantially reduced (e.g., 20-30%)" price overseas for its dural sealant products (as compared to Integra's products). (D.I. 94 at 7-8) During his deposition, Mr. Lenox explained that the basis for this "20-30%" figure was a "report that came in from the U.K. sales team [that] told us that that is the pricing that the hospital was given for the Adherus product relative to the price of DuraSeal." (First Pivovar Decl., ex. E at 36-37) This "report" does not appear to be in the record, nor are there any further details in the record about the report. But even if there were, and even if the report's contents were what Mr. Lenox suggests, that would simply establish that HyperBranch gave one single hospital in the United Kingdom a price for an Accused Product that was 20-30% below DuraSeal's price. It could not amount to a solid basis for the claim that there was, overall, a 20-30% price differential between the parties' products overseas. Indeed, approximately four months before he executed his declaration (the one

[14] Mr. Jarosz explains that a GPO is an organization that negotiates purchasing contracts for a wide variety of products in the medical field for its membership to access. (First Pascale Decl., ex. 4 at ¶ 81)

providing the "20-30%" figure), [redacted] When pressed about this during his deposition, Mr. Lenox ended up testifying that he does not actually "know about the actual pricing" of HyperBranch's and Integra's dural sealant products overseas, and that if he were given the opportunity, he might amend his declaration to state that "in certain countries [HyperBranch's products] might be priced at parity." (*Id.* at 49)

Second, even if there *were* some strong record support for the idea that HyperBranch's products are marketed at [redacted] discounts over Integra's products overseas, there would be little support for the claim that the AutoSpray product will be priced [redacted] lower than DuraSeal (or anything close to that) here in the United States. To the contrary, HyperBranch's Chief Executive Officer ("CEO") and Chief Operating Officer ("COO") Jeffrey G. Clark explained that "[w]hile pricing variables in the dural sealant market makes absolute comparisons difficult, HyperBranch's competitive strategy is to [redacted]." (D.I. 94 at 8 (citing Clark Decl. at ¶ 25; Kidder Decl. at ¶¶ 25, 27)) Indeed, [redacted]. (Clark Decl. at ¶ 24; *see also* D.I. 94 at 8)

Instead, the evidence of record indicates that the current average selling price in the U.S. of Integra's and HyperBranch's products is roughly similar. Mr. Lenox testified in January 2016

that he believed the average selling price for DuraSeal to be "in the range of $800[,]" (First Pivovar Decl., ex. E at 101), and a survey of certain of HyperBranch's distributors indicated an average selling price for the AutoSpray product of between [redacted] per unit, (Kidder Decl. at ¶ 73; Clark Decl. at ¶ 26). Moreover, in Mr. Jarosz's supplemental declaration, he most clearly calculates the average sale price of the AutoSpray product in the United States (based on the reports by the HyperBranch distributors) to be [redacted], a figure that is [redacted] lower than the (roughly) $800 average price of DuraSeal. (Second Pascale Decl., ex. 22 at ¶ 30)[15]

Third, even if the evidence supported the notion that the AutoSpray product has been, on average, priced at least some amount below the DuraSeal product in the United States, the evidence does not indicate that this has yet caused Integra to actually lower the price of DuraSeal in response. If anything, the evidence suggests that, to date, DuraSeal's prices have been following the opposite trajectory. Integra has actually increased DuraSeal's list price [redacted] since 2014, [redacted] after the AutoSpray product's entry onto the U.S. market. (D.I. 94 at 8 n.3 (citing First Pivovar Decl., ex. E at 25, 26, 28); Kidder Decl. at ¶¶ 74-77) That is not the hallmark of a product whose margins are decreasing (although it is of course possible that Plaintiffs could be forced lower the price of DuraSeal in the future). *Cf. Graceway Pharms., LLC v. Perrigo Co.*, 722 F. Supp. 2d 566, 578

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[15] Mr. Lenox later filed a supplemental declaration of his own in April 2016, in which he stated that "a number" of the hospitals "considering trialing have indicated that one of the main reasons for trialing the Adherus product is because the Adherus product is priced lower than DuraSeal." (Second Pascale Decl., ex. 21 at ¶ 5) But again, Mr. Lenox provides no real detail here—no information about which hospitals he is referring to, how many make up "a number," nor any further information as to just how much lower the AutoSpray product is supposedly being priced than the DuraSeal product. The Court cannot give any weight to such vague and speculative evidence.

(D.N.J. 2010) (noting that "the fact that [the price for plaintiff's product] is now higher, undermines, to some extent, [the plaintiff's] position in regard to lost market share").

Fourth, as noted above, a component of Plaintiffs' price erosion theory is the assumption that HyperBranch will enter into contracts with GPOs (forcing Integra to do so as well, to its economic detriment). But here again, there is no evidence that this is actually happening or that it will happen soon. (*See* D.I. 94 at 9 n.4) For example, Mr. Clark reports that HyperBranch "has not entered into any contracts with any [GPOs]" since the AutoSpray product's launch, nor does HyperBranch "have any intention to enter into any contracts that will lower the price of Adherus in the marketplace, with GPOs or otherwise." (Clark Decl. at ¶ 27) And as for Integra, as of January 2016, Mr. Lenox testified that it too had not yet been forced to sell through GPOs, [redacted] Again here, then, a healthy amount of speculation is baked into Plaintiffs' argument.

Based on all of the above-referenced holes in Plaintiffs' price erosion theory, the Court concludes that Plaintiffs have not demonstrated that there is an imminent threat of substantial price erosion. This theory, then, cannot amount to support for Plaintiffs' claim of irreparable harm. *See, e.g.*, *Wavetronix LLC v. Iteris, Inc.*, No. A-14-CA-970-SS, 2015 WL 300726, at *8 (W.D. Tex. Jan. 22, 2015) (concluding that the plaintiff's forecast of price erosion "weigh[ed] against a finding of irreparable harm" where the defendant challenged the plaintiff's argument that the accused product was priced consistently lower than plaintiff's product, and both parties acknowledged that the price of their products changed from commercial contract to

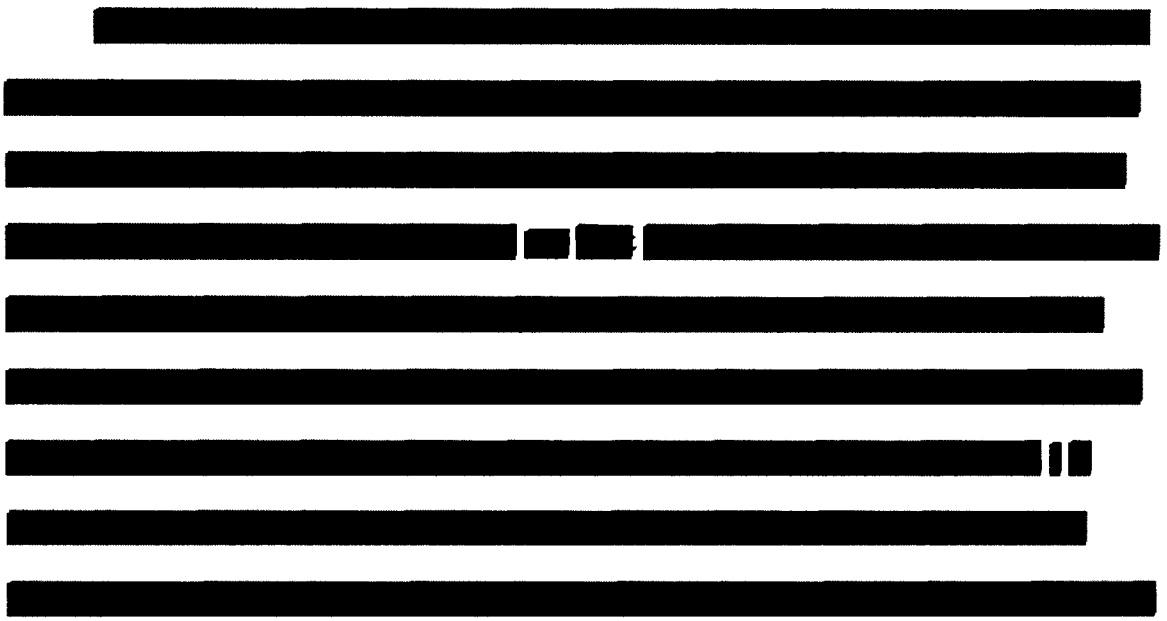
contract—leaving the court "unclear as to whether the non-quantifiable threat to [plaintiff] from sales of [defendant's product] . . . looms as large as [plaintiff] represents"); *MicroAire Surgical Instruments, LLC v. Arthrex, Inc.*, 726 F. Supp. 2d 604, 640 (W.D. Va. 2010) ("The mere assertion that allowing a competitor to keep producing and selling an allegedly infringing product will lead to irreversible price erosion, without more, is insufficient to constitute a finding of irreparable harm.").

d. Loss of synergy

Plaintiffs next assert that Integra acquired the DuraSeal product line to complement DuraGen, Integra's line of dural graft products, and that HyperBranch's alleged infringement would "substantially harm" Integra's strategy to market their product portfolio "synergistically" "across the entire dural closure market." (D.I. 9 at 17-18) In support, Plaintiffs again cite to the declarations of Mr. Lenox and Mr. Jarosz. (*Id.* (citing First Pascale Decl., ex. 3 at ¶¶ 9, 12; *id.*, ex. 4 at ¶¶ 84-85))

But in order to demonstrate that the presence of the AutoSpray product in the U.S. market will disrupt "synergistic" sales of DuraGen with DuraSeal, presumably Plaintiffs would need to show that, in fact, such sales-related synergies actually existed (or were likely to occur in the future) at the time of the AutoSpray product's market entry. And yet Mr. Lenox's and Mr. Jarosz's declarations do not do that. At most, they speak in terms of what Integra apparently *aspired for* with respect to synergies as to sales of DuraSeal and DuraGen. (*See, e.g.*, First Pascale Decl., ex. 3 at ¶ 12 (Mr. Lenox stating that HyperBranch's entry into the United States market would "divert Integra's offensive marketing efforts away from Integra's *strategic plan* designed to simultaneously establish DuraSeal® and DuraGen®" and therefore "the synergy

between the DuraSeal and DuraGen products[] will be substantially harmed") (emphasis added); *id.*, ex. 4 at ¶ 84 (same)) The evidence does suggest, at least, that when Integra was acquiring the DuraSeal line, it touted potential synergies between the product lines to its investors. For example, an October 2013 Integra investor presentation states that the combination of DuraGen and DuraSeal "allows Neurosurgery division to address both dural graft and dural sealant markets" and "[d]epending on the ability to suture, one or both surgical products may be used." Integra LifeSciences Corp., *Integra Acquires DuraSeal Product Line from Covidien*, Slide 5 (October 28, 2013), http://files.shareholder.com/downloads/IART/0x0x700709/7B9C7519-ECE4-4867-AC3A-C57FAAE30ECD/DuraSeal/Investor_Presentation_10.28.2013_.pdf. (last visited Aug. 8, 2016) (*cited in* First Pascale Decl., ex. 4 at ¶ 84 n.131). But the DuraSeal acquisition closed over two and a half years ago, and so Plaintiffs' failure to "present any evidence that alleged synergies between DuraSeal and DuraGen lead to additional sales of either product" undercuts the strength of this theory of irreparable harm. (D.I. 94 at 9)



[redacted]

In the end, Plaintiffs have not demonstrated that any real synergy exists as to the sales of Integra's DuraSeal and DuraGen products. And so, Plaintiffs' assertion that sale of the AutoSpray product in the U.S. will cause them harm because it will disrupt such synergies is unsubstantiated on this record. It cannot be a basis for a finding of irreparable harm.

e. Reputational harm

Lastly, Plaintiffs make an argument about the reputational harm that will befall their products as a result of the U.S.-based sale of the AutoSpray product. Just as with many of Plaintiffs' arguments regarding harm set out above, however, this one is also built on a weak evidentiary foundation.

Indeed, even Plaintiffs characterize this type of harm as wholly speculative, asserting that HyperBranch's products "*could* result in . . . *potential* adverse reputational effects to hydrogel sealants . . . . *if* those products cause any injury that would not have been caused by use of the Integra products." (D.I. 9 at 16, 18 (emphasis added); *see also id.* at 18 ("Improper use of HyperBranch's [] AutoSpray [product] in the U.S. (such as off-label use in the spine[)] *could* damage the image of all hydrogel sealants[.]") (emphasis added)) In providing background regarding why Integra has this fear, Mr. Lenox explains that when DuraSeal first entered the market, it was only approved for cranial use, but "many" surgeons used it off-label in the spine, resulting in "a number" of adverse events. (First Pascale Decl., ex. 3 at ¶ 13) After reporting this, Mr. Lenox then leaps to a prediction: that it is "extremely likely" that off-label use of HyperBranch's product in spinal procedures will occur, and that they will "cause patient injur[ies]

(e.g., pain or paralysis)." (*Id.*) He asserts that this will, in turn, ultimately mar the reputation of all hydrogel sealants. (*Id.*)

These allegations do not provide enough specificity to be convincing. The Court is left wondering, for instance, about the following: (1) What was the magnitude of off-label use of DuraSeal?; (2) How many "adverse events" occurred as a result of those uses, and what was the nature of those "adverse events"?; (3) How widely publicized were those events, and in what way and to what degree did they mar the reputation of Integra's DuraSeal product?; and (4) Why does Integra believe that, years after physicians made these off-label mistakes as to DuraSeal, others would now likely repeat those same mistakes with the AutoSpray product? Mr. Lenox's declaration, however, provides no answers to these questions. Moreover, it is also not clear to the Court why Plaintiffs' hypothetical scenario—off-label use of the AutoSpray product for spinal uses—would negatively impact the reputation of the *DuraSeal* product line, which has for years included products specifically FDA-approved for cranial uses (DuraSeal Dural Sealant) and for spinal uses (DuraSeal Exact Spine Sealant). (D.I. 9 at 18)

Here too, then, Plaintiffs' reputational harm theory falls far short of establishing that irreparable harm "is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis in original); *see Caldwell Mfg. Co. N. Am., LLC v. Amesbury Grp., Inc.*, No. 11-CV-6183T, 2011 WL 3555833, at *4-5 & n.1 (W.D.N.Y. Aug. 11, 2011) (concluding the same, where the only evidence submitted by the plaintiff in support of its reputational harm argument was speculative statements from two of the plaintiff's employees).

f. Conclusion

In sum, Plaintiffs have made no showing that they have yet suffered any meaningful actual

harm from the introduction of HyperBranch's AutoSpray product in the United States market. And where they have claimed they will likely face future harm, their arguments (and the proffered evidence in support thereof) were often unduly speculative or otherwise deficient. The nature of the harm asserted here thus does not weigh in favor of a grant of the Motion.

3. Adequacy of money damages

HyperBranch argues that to the extent that Plaintiffs do face future harm from patent infringement, any such harm will be adequately compensable by money damages. (D.I. 94 at 9-10) It is well settled that "there is no *presumption* that money damages will be inadequate" in connection with a motion for preliminary injunction—"[s]ome evidence and reasoned analysis for that inadequacy should be proffered." *Nutrition 21*, 930 F.2d at 872 (emphasis added).

In asserting that they have provided the requisite "evidence and reasoned analysis," Plaintiffs first re-state the various forms of harm they will face in the absence of an injunction (such as impairment of growth opportunities, price erosion, loss of synergy, and potential adverse reputational effects), and then go on to argue that the magnitude of that harm would be difficult to quantify. (D.I. 9 at 16) Yet, even if such harms could be difficult to quantify, a plaintiff first needs to establish that they are imminent and substantial. And there, as noted above, Plaintiffs' proofs were not particularly compelling.

Plaintiffs otherwise argue, citing to Mr. Jarosz's declaration, that "[i]t would be difficult, if not impossible, to calculate how many existing or potential customers chose to purchase HyperBranch's [] products instead of Integra's products." (*Id.* (citing First Pascale Decl., ex. 4 at ¶¶ 73-79)) In his declaration, Mr. Jarosz explained that this would be an especially challenging task in this case because DuraSeal was only "acquired and re-positioned" by Integra in 2014, and

because estimating DuraSeal's "but-for performance in a no-entry world in which it never faced competition from Adherus" is hard to do with accuracy and certainty. (First Pascale Decl., ex. 4 at ¶¶ 75, 77-78)[16] But when further pressed on this in his deposition, Mr. Jarosz acknowledged that beyond the fact of Integra's 2014 acquisition of the DuraSeal line, there is nothing unique about this case that would make forecasting such damages any more difficult than it would be in any other case. (D.I. 150 at 5 (citing Second Pivovar Decl., ex. QQ at 100-05))

As for the timing of the Integra acquisition, it is true that it came only two and a half years ago. Mr. Jarosz suggests that the "post-Integra" timeframe is particularly important to a damages analysis (because Integra has promoted the product in a more robust way than it had been promoted in the past, such that pre-Integra sales are less insightful than post-Integra sales as part of a future damages analysis), and that the short post-Integra sales time period provides "very little base" for an accurate sales projection going forward. (Second Pivovar Decl., ex. QQ at 102) However, the DuraSeal product line has been in existence since at least 2005, (First Pascale Decl., ex. 4 at ¶ 20), and even Mr. Jarosz acknowledges that pre-Integra sales data from 2005-2014 will still be *useful* in making sales/damages projections, (Second Pivovar Decl., ex. QQ at 103). So too, presumably, would be what is now two and a half years' worth of post-Integra sales data. Moreover, Mr. Jarosz admitted that Integra was itself able to make annual projections of DuraSeal sales in 2015 prior to the beginning of that year—projections that assumed that HyperBranch's AutoSpray product would enter the market mid-year. (*Id.* at 100)[17]

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[16] Mr. Jarosz notes that the "timing of lawful generic entry will not be until 2024." (First Pascale Decl., ex. 4 at ¶ 77)

[17] Covidien was also able to prepare forecasts in 2013 as to what impact the sale of the AutoSpray product in the United States would have on DuraSeal's market share. (*See, e.g.*,

Estimating future damages with less than perfect information is never easy. And perhaps Integra's relatively recent acquisition of the DuraSeal line makes that task a bit harder here. But there are plenty of data points for Plaintiffs' expert to work with in that effort. In light of that, and Plaintiffs' insufficient showing regarding imminent and substantial harm, Plaintiffs have not met their burden to demonstrate that monetary damages would inadequately compensate any such harm. *See Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 500-01 (D.N.J. 2015) (concluding that plaintiff failed to demonstrate that the loss of market share, sales, and price erosion are incapable of calculation; "[r]ather, [plaintiff] demonstrated, at most, that the exact calculation of the damages may prove a difficult endeavor, but that too fails to make a sufficient case for irreparable harm") (citing cases).

4. Nexus

A showing of irreparable harm requires proof that a "causal nexus relates the alleged harm to the alleged infringement." *Apple II*, 695 F.3d at 1374; *see also Apple I*, 678 F.3d at 1324 ("Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature."). The nexus requirement is a "way of distinguishing between irreparable harm caused by patent infringement and irreparable harm caused by otherwise lawful competition—e.g., 'sales [that] would be lost even if the offending feature were absent from the accused product.'. . . [t]he former type of harm may weigh in favor of an injunction, whereas the latter does not." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 735 F.3d 1352, 1361 (Fed. Cir. 2013) ("*Apple III*") (citation omitted).

The analysis is a "flexible" one, satisfied upon a showing by the patentee that there is

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Second Pivovar Decl., exs. LL, RR, SS)

"some connection between the patented features and the demand for the infringing products." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 809 F.3d 633, 641 (Fed. Cir. 2015) ("*Apple IV*") (internal quotation marks and citation omitted).[18] The Federal Circuit has explained that showing "some connection" between the patented feature and consumer demand may be accomplished in a number of ways—including, for example, "with evidence that a patented feature is one of several features that cause consumers to make their purchasing decisions[,]" "evidence that the inclusion of a patented feature makes a product significantly more desirable[,]" and "evidence that the absence of a patented feature would make a product significantly less desirable." *Apple III*, 735 F.3d at 1364.

Plaintiffs attempt to make the requisite showing of nexus in the following way. First, they note that their technical expert, Dr. Jimmy W. Mays, explained that the asserted patents "in some cases cover many general aspects of hydrogel sealants." (First Pascale Decl., ex. 13 at ¶ 36) Integra points, for example, to claim 17 of the '5705 patent (which depends on claim 1), which claims, in pertinent part:

> **1.** A method of making *a biocompatible* degradable hydrogel to treat a medical condition of a patient comprising: identifying a medical condition for treatment by use of a hydrogel formed in situ in a patient and *fully degradable in a patient* in less than about 180 days; and mixing a first precursor with a second precursor in situ in *the patient to form the hydro gel* for treatment of the medical condition . . . .

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[18] While this particular *Apple* case involved discussion of a permanent injunction, the Court drew on decisions relating to preliminary injunctions in assessing the causal nexus requirement, as the "the substantive analysis for [the] irreparable harm factor is the same[.]" *Apple IV*, 809 F.3d at 652 n.3 (Reyna, J., concurring); *see also Apple III*, 735 F.3d at 1361 (explaining that the causal nexus requirement "applies equally to the preliminary and permanent injunction contexts").

> **17.** The method of claim **1** wherein the hydrogel is essentially *fully degradable in a patient* in less than about 90 days.

(First Pascale Decl., ex. 10, cols. 30:34-41, 32:16-17 (emphasis added)) And then, in order to make out the required showing of nexus, Plaintiffs cite to the testimony of Dr. John M. Tew, a Professor of Neurosurgery, Radiology and Surgery and administrator at the University of Cincinnati College of Medicine, who is a fact witness for HyperBranch. (D.I. 121 at 9 (citing Second Pascale Decl., ex. 3 at 85-87); Tr. at 110) In response to questioning from Plaintiffs' counsel during his deposition, Dr. Tew agreed that the Accused Products provide the following "important" features (all of which are mentioned in, *inter alia*, the claim listed above): (1) they form a hydrogel on the patient; (2) the hydrogel is biocompatible; and (3) it degrades inside the body of a patient. (D.I. 121 at 9 (citing Second Pascale Decl., ex. 3 at 85-87)) Dr. Tew agreed that the fact that the products contain these features constitute reasons why neurosurgeons want to use the products. (*Id.*; *see also* Tr. at 109 (Plaintiffs' counsel asserting that "if [the AutoSpray product] didn't have these [basic patented features], [neurosurgeons] wouldn't buy it at all because it wouldn't be a dural sealant"); Plaintiffs' Preliminary Injunction Presentation, Slide 69)

To understand what Plaintiffs are arguing here, it is helpful to look at that argument on a more granular level. Take, for example, one of the asserted "patented features" called out by Plaintiffs: the biodegradability of the patented hydrogel in a patient. As noted above, Dr. Tew mentioned that the fact that the AutoSpray product degrades inside a patient's body is something that is important to making the product attractive to physicians.[19] (Second Pascale Decl., ex. 3 at

[19] In his declaration, Dr. Tew actually (and more specifically) notes that the AutoSpray product's "slower rate of degradation in the body" as compared to DuraSeal is something that is "particularly important to most surgeons." (D.I. 98 at ¶¶ 9-10)

85-87; *see also* Tr. at 14) Indeed, in its advertising, HyperBranch promotes the fact that its AutoSpray product is "[b]iodegradable" as one of the product's attractive and defining features. (First Pascale Decl., ex. 14 at 2) And, as was also mentioned above, the asserted patents (including the '5705 patent) claim a "degradable" hydrogel that is "fully degradable" in the body. And so, since physicians would not use the AutoSpray product as dural sealants unless it was, *inter alia*, a "fully degradable" "hydrogel," Plaintiffs argue that they have shown "some connection" between a "patented feature" and the purchase of the allegedly infringing product.

The Court is uncertain, however, that this is the right way to assess the "nexus" test here. No one in this case, including Plaintiffs, is suggesting that at the time of the issuance of the asserted patents, Plaintiffs could have obtained a patent on a "hydrogel" or even a "fully degradable" hydrogel—full stop. Those *words* are certainly in the patent claims (like claim 17 of the '5705 patent), but the asserted patents are really directed to *particular features or components* of hydrogels—i.e., those with color added to determine thickness, and to hydrogels made in certain purportedly inventive ways. (*See, e.g.*, '034 patent, col. 2:18-24; '3705 patent, cols. 6:49-52, 6:66-7:16; '5705 patent, cols. 4:13-17, 5:58-62) And also, it is not clear to the Court that the "demand for the infringing products" is due to the fact that they produce a "degradable" "hydrogel"; if anything, the fact that the AutoSpray product (or the DuraSeal product) produce degradable hydrogels seems to be taken as a given by physicians like Dr. Tew. The question here would be whether there is "some connection" between patentee's asserted *improvement over the prior art* and the decisions of physicians to choose the AutoSpray product because that product (allegedly) embodies and/or utilizes such improvements. *See Marine Travelift, Inc. v. ASCOM SpA*, No. 14-C-443, 2014 WL 4215925, at *16-17 (E.D. Wis. Aug. 25, 2014) (where the

plaintiff's nexus argument was that customers viewed its technology as the driving force in the decision to buy defendant's product, and where the plaintiff suggested this by pointing to evidence that customers preferred a product that included carousel steering, the Court explained that "the problem with this line of argument is that [plaintiff's] patent is not a patent on the general idea of carousel steering, which had already existed. As relevant here, the [patentee's] invention is actually a disclosure involving the use of two wheels in reverse to achieve the proper carousel position. Thus, even if it is true that customers wanted carousel technology *in general*, that fact is irrelevant because carousel movement is not the patented technology. Instead, the salient question is whether any customers wanted [*plaintiff's*] way of achieving carousel technology. . . . there was not even a hint of testimony or evidence that any customer viewed *that* technology (rather than generic carousel technology) as even a factor in the purchasing decision") (emphasis in original); *see also Rudolph Techs., Inc. v. Camtek Ltd.*, Civil No. 15-1246 ADM/BRT, 2015 WL 5039295, at *15 (D. Minn. Aug. 26, 2015) ("Thus, to establish . . . nexus, Rudolph must show that customers buy the Eagle because it is equipped with the specific technology recited in Claim 1 of the [asserted] patent—not because it inspects semiconductors in general."); *cf. Hydrodynamic Indus. Co. Ltd. v. Green Max Distribs., Inc.*, No. 2:12-cv-05058-ODW(JEMx), 2014 WL 2740368, at *2 (C.D. Cal. June 16, 2014) (asking, in evaluating the nexus issue, how the patent at issue "improved upon the prior art[,]" and then going on to assess whether such improvements found in the accused product propelled customer demand for that product).[20] And here, Plaintiffs

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[20] This concept may have been best articulated by the Federal Circuit in *Apple III*:

> To illustrate these points, it may be helpful to return to an example discussed in *Apple II*. There, we explained that a battery does not necessarily drive demand for a laptop computer simply because its removal would render the laptop ineffective

have not sufficiently articulated what are the particular improvements to hydrogels said to be captured by the representative claims in the asserted patents, and why *those improvements* are factors that impact physicians' decisions to use the AutoSpray product.

Moreover, the record is replete with compelling evidence that the AutoSpray product is an attractive choice over DuraSeal due to a feature that undisputedly has *nothing to do with* the asserted patents—its applicator. (D.I. 94 at 10; D.I. 150 at 1-3) This evidence unquestionably shows that: (1) DuraSeal's applicator was associated with significant problems; (2) the AutoSpray product's applicator did not have such problems; and (3) this would be an important reason (perhaps *the primary* reason) why physicians and hospitals would choose the AutoSpray product over the DuraSeal product.

One such category of evidence is the content of declarations offered by HyperBranch's neurosurgeon fact witnesses. Dr. G. Alexander West, the Chief of Neurosurgery and Director of Spine Services at Houston Methodist Neurological Institute West Hospital in Houston, Texas, explained that as compared to DuraSeal, HyperBranch's product "is [] easier to use, with a self-powered spray system that helps achieve a controlled, even distribution of sealant." (D.I. 99,

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> as a portable computer. [] That is because consumers often do not choose a laptop based on its battery, and presumably at this point, no inventor has a patent covering all laptop batteries. Nevertheless, it is indisputable that the ability to carry around a computer without having to plug it in is one of the reasons people buy laptops. Thus, if the first person to invent a laptop battery had obtained a patent covering all laptop batteries, then it would be reasonable to say that the patented invention was a driver of demand for laptops. And if a particular patented laptop battery lasts significantly longer than any other battery on the market, then the replacement of that battery with a noninfringing battery might make a laptop less desirable. In that case, it might be reasonable to conclude that the patented battery is a driver of consumer demand for the laptop.

Apple III, 735 F.3d at 1364-65.

Declaration of Dr. G. Alexander West ("West Decl."), at ¶¶ 1, 9) Unlike his experiences with DuraSeal's applicator, Dr. West "never had a clogging issue" with the AutoSpray product. (*Id.* at ¶ 9) And Dr. Carl Hardwidge, a Consultant Neurosurgeon with the Brighton and Sussex University Hospital Trust in the United Kingdom, explained that he "like[d] the even distribution delivered by [the AutoSpray product's] spray applicator and the ability to switch to a smaller, non-spray applicator for access to tight spaces." (D.I. 100, Declaration of Carl Hardwidge ("Hardwidge Decl."), at ¶¶ 1, 7)

These neurosurgeons' opinions are underscored by Plaintiffs' (and their predecessor-in-interest Covidien's) *own documents*, which are rife with references to the AutoSpray product's improved applicator, to unresolved problems with DuraSeal, and to Covidien's/Integra's plans to develop a better applicator for DuraSeal that appear not have come to fruition. Some excerpts are summarized below:

- An August 2009 e-mail communication produced by Covidien giving the "skinny on the Hyper[B]ranch dural sealant" explained that HyperBranch's interveiws with "many" DuraSeal users revealed that the "main complaint is the delivery system." The e-mail said that HyperBranch's product (then undergoing safety and efficacy studies) would "have a proprietary delivery system[.]" (Second Pivovar Decl., ex. FF)

- An August 2010 e-mail communication produced by Covidien highlighted a need to "improve the performance of [DuraSeal]" including by developing a "better applicator" to "protect [the DuraSeal] business[,]" because HyperBranch's AutoSpray product "supposedly [has] a far superior applicator to ours." (*Id.*, ex. GG)

- A June 2012 Covidien presentation regarding the development of a new applicator for DuraSeal stated that "customers are *not satisfied* with [DuraSeal's] clogging and spray pattern" and that HyperBranch's "strategy will focus on the 'AutoSpray' novel applicator, designed to provide a consistent, reproducible spray pattern[.]" (*Id.*, ex. KK (emphasis in original))

- A June 2012 e-mail communication produced by Covidien in which the author states "[w]e need to develop one like this" in reference to the AutoSpray product's applicator. (*Id.*, ex. II)

- September 2012 e-mail communications produced by Covidien, in which the author of one e-mail states that "[a]ll we need is the new applicator [for DuraSeal] sooner rather than later and we can hold this off . . .[,]" in reference to HyperBranch's impending launch. (*Id.*, ex. JJ)

- October 4, 2012 e-mail communications among Covidien employees concerning a project to "produce a new applicator" reveals that the project originated "to address a market need/surgeon complaint" with respect to inconsistent applications of the hydrogel from DuraSeal's applicator depending upon the surgeon's thumb pressure. (D.I. 144, ex. Y) This e-mail reported that HyperBranch would be launching a dural sealant product with "a new, sexy applicator" and that Covidien's marketing team was "very worried [that HyperBranch's applicator] will erode our [U.S.] sales of DuraSeal." (*Id.*)

- A March 2013 Covidien DuraSeal Sealant Applicator Market Assessment noted that "[i]f DuraSeal were improved so that it did not clog, it would deter 49% of surgeons from trialing/switching to another product." (First Pivovar Decl., ex. M at COV0000966)

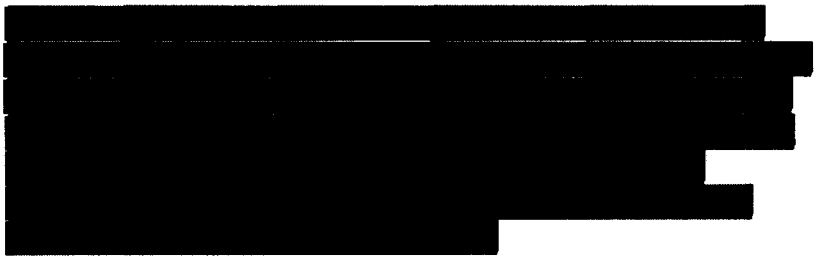
- A March 22, 2013 Integra presentation regarding "Hyena"—which appears to have been an Integra-internal code name for HyperBranch—stated that "Hyena appears to address key unmet market needs" such as a "[m]arket need for higher and longer lasting burst strength" and "[m]arket need for a better sealant applicator." (*Id.*, ex. U at INT00032085; *see also* Kidder Decl. at ¶ 93 n.158)

- An April 2013 e-mail communication from a Covidien employee reported that the company's "biggest problem" regarding DuraSeal is "our past history with the [product] and how hard we still have to work every day to overcome all of the issues that occurred in the past and never evolving with improvements in the product to correct those issues in the head[.]" (Second Pivovar Decl., ex. HH) The e-mail highlighted some examples of these DuraSeal issues, including that: (1) "[o]ne of the busiest neurosurgeons in the country will not use [DuraSeal] because of past product issues

(leaks/infections)"; (2) one of the company's busiest neurological customers, a hospital, stopped using [DuraSeal] "because of infections"; (3) a neurosurgeon reported a problem regarding "the applicator"; and (4) neurosurgeons in the Tennessee region "will not use the product because of the swell issue." (*Id.*) The employee conveyed his "belief [] that most if not all of the problems come[] from the applicator design and best practice" which "go hand and hand when you are doing [cranial procedures]." (*Id.*) The e-mail closed by noting that HyperBranch "knows this is our weakness and they plan to fully capitalize on the opportunity with an improved applicator and product set up." (*Id.*)

- A May 2013 Covidien Presentation predicted that the top reason for neurosurgeons to switch from DuraSeal to Adherus was "[c]logging" and noted that "[i]mprovements to the [DuraSeal] [a]pplicators can address the major concerns[,]" which also included an inconsistent spray. (First Pivovar Decl., ex. N at COV0001815)

- In June 2013 e-mail communications among Covidien employees, a Clinical Project Manager having difficulty enrolling neurosurgeons in a DuraSeal Exact Spine Sealant post-approval study noted her "understand[ing] that HyperBranch is about to launch and that they have a special applicator that limits variability in the way the product is applied[,]" and further questioned whether "we had something like this in the pipeline?" (*Id.*, ex. S at COV0000377) Covidien's Director of Product Development replied that a next generation application would be designed with "an automatic trigger applicator that will . . . . allow for start/stop applications and will deliver a consistent, ideal layer of DuraSeal every time" and would "be a nice competitive response to the HyperBranch applicator." (*Id.* at COV0000375)

- 

And even the Declaration of Plaintiffs' own neurosurgeon fact witness, Dr. Timothy Lucas (a "consultant" for Integra who was not compensated for submission of his declaration),

highlights these problems with DuraSeal. (Second Pascale Decl., ex. 8 at ¶¶ 3, 10-11) Dr. Lucas, an Assistant Professor of Neurosurgery and administrator at the Hospital of the University of Pennsylvania, has never used HyperBranch's AutoSpray product. (*Id.* at ¶¶ 1, 12) However, he opined that "[i]n all the surgeries that [he] participated in that used *properly applied* DuraSeal," he never observed issues with swelling, the product's longevity, or clinically-significant CSF leaks due to the product's burst strength being too low. (*Id.* at ¶¶ 10-11 (emphasis added)) In this context, Dr. Lucas' "properly applied" qualifier is a significant one, since the above-referenced documents paint a picture of a product that could, in fact, be rather difficult for a surgeon to properly apply. (*See also* D.I. 144, ex. BB (Integra document noting that Dr. Lucas [redacted], he could see how clogging could occur when used))

In light of the above-referenced factors, the Court concludes that even to the extent that Plaintiffs can be said to have demonstrated "some connection" between a patented feature and allegedly infringing sales, the connection is not a strong one and does not well support their overall claim of irreparable harm. *Cf. Apple IV*, 809 F.3d at 641-42 (explaining that "[w]hen a patentee alleges it suffered irreparable harm stemming from lost sales solely due to a competitor's infringement, a finding that the competitor's infringing features drive consumer demand for its products satisfies the causal nexus inquiry" as "[i]n that case, the entirety of the patentee's alleged harm weighs in favor of injunctive relief" but, on the other hand, where "the infringing features are not the only cause of the lost sales[, that fact] may well lessen the weight of any alleged irreparable harm").

5. Conclusion

The irreparable harm factor clearly weighs against granting Plaintiffs' requested relief. First, Plaintiffs' short delay in filing their Motion is a factor that, to a small degree, works against Plaintiffs' request. Second, and much more significantly, Plaintiffs were required to set out how, absent an injunction, they faced "substantial and immediate irreparable injury" from the sale of the AutoSpray product. But, the evidence as to the various proffered forms of irreparable harm shows, to the contrary, that Plaintiffs have not yet faced much (if any) real harm from that product. That evidence also suggests that any future harm will be long-developing. Third, and relatedly, Plaintiffs have not demonstrated that any harm that they have or will face could not be adequately compensated by money damages. And fourth, Plaintiffs have not made a strong showing of a nexus between any harm they face and the patented features of the Accused Products. All of these conclusions come together to clearly demonstrate that the irreparable harm factor favors HyperBranch.

Plaintiffs' failure to demonstrate irreparable harm alone is enough to warrant denial of the Motion. *See, e.g.*, *Chestnut Hill Sound Inc.*, 2015 WL 6870037, at *6. However, as the Court will briefly discuss below, the remaining two factors also weigh in favor of denying the Motion.

C. Balance of the Hardships

"An injunction should not be granted if its impact on the enjoined party would be more severe than the injury the moving party would suffer if it is not granted." *Litton Sys., Inc. v. Sundstrand Corp.*, 750 F. 2d 952, 959 (Fed. Cir. 1984). And when considering the "balance of the hardships" factor, among other things, it is appropriate for courts to consider the relative sizes of the parties. *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 708 (Fed.

Cir. 1997).

Plaintiffs suggest (with no supporting citation to the record) that any harm HyperBranch would face if an injunction were granted would not be significant, in part due to the fact that HyperBranch could still sell its products overseas. (D.I. 9 at 19; Plaintiffs' Preliminary Injunction Presentation, Slide 70) But to the contrary, Mr. Clark's declaration states that if HyperBranch is enjoined from selling the AutoSpray product in the United States, [redacted] (D.I. 145 at ¶ 7) According to Mr. Clark, [redacted] if the Court grants Plaintiffs' Motion. (*Id.* at ¶ 9) [redacted] Mr. Clark states, HyperBranch [redacted] (*Id.* at ¶¶ 11, 13)[21]

The size of the parties is also instructive here. There is little dispute that HyperBranch is a

[21] Plaintiffs have not put into the record any evidence calling into doubt the accuracy of these statements by Mr. Clark. And so, they stand essentially unrebutted. Plaintiffs *did* argue that Mr. Clark's statements are based on inadmissible hearsay and should not be considered, (Tr. at 110-11; Plaintiffs' Preliminary Injunction Presentation, Slide 70), but the Court is not persuaded. For one, Mr. Clark's testimony in this regard is based on more than just what some investors said to him—it is also clearly drawn from his own experience as CEO and COO of HyperBranch. And even to the extent certain portions of Mr. Clark's testimony are based on hearsay, courts may exercise their discretion in weighing hearsay materials given the character and objectives of preliminary injunction proceedings. *See, e.g., Astrazeneca AB v. Camber Pharms., Inc.*, Civ. No. 15-927-SLR, 2015 WL 7307101, at *3 n.6 (D. Del. Nov. 19, 2015).

small enterprise. It has 13 employees, and its total global sales revenues in 2015 were under [redacted] (Clark Decl. at ¶¶ 4, 28) As of early 2016, its United States sales in the dural sealant market amounted to less than [redacted] of that market. (D.I. 144, ex. X at 214) In contrast, Integra's global revenues in 2014 were nearly $1 billion, (First Pascale Decl., ex. 4 at ¶ 13), with sales of DuraSeal in the United States totaling [redacted] in 2014, (*id.* at ¶ 14). Thus, as HyperBranch notes, its product's impact (at least so far) on Integra's sales revenues in the United States has been "negligible." (D.I. 144 at 8)

In sum, the evidence suggests that were the instant Motion granted, [redacted] On the other hand, denial of the Motion would (at least in light of the current record) leave Plaintiffs "in roughly the same position they are [in] currently." (*Id.*) Taking these facts into consideration, the Court finds that the balance of the hardships factor weighs in favor of denial of Plaintiffs' Motion. *See Advanced Commc'n Design, Inc. v. Premier Retail Networks, Inc.*, 46 F. App'x 964, 985 (Fed. Cir. 2002) (noting that "we cannot discount [defendant's] sworn assertions that a preliminary injunction could well cause the company to dissolve" in consideration of this factor); *Upjohn Co. v. Riahom Corp.*, 641 F. Supp. 1209, 1221 (D. Del. 1986) (finding that the balance of the hardships factor favored defendants, where issuance of a preliminary injunction with regard to claims of patent infringement "presumably would put [the defendant corporation] out of business" while "if no injunction issues, [plaintiff] will be in approximately the same position as it is now"); *cf. EMC Corp. v. Zerto, Inc.*, C.A. No. 12-956(GMS), 2016 WL 1291757, at *14 (D. Del. Mar. 31, 2016) (denying a permanent injunction and holding that the balance of the hardships factor "weighed strongly against" grant of the requested relief where "[t]he products [plaintiff] targets with this injunction comprise the

entirety of [defendant's] business" and "[i]n contrast, the lost sales [plaintiff] identifies represent about 0.001% of its annual revenues").[22]

D. Public Interest

As to the final factor, on the one hand, "public policy favors protection of the rights secured by [] valid patents." (D.I. 9 at 20 (quoting *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983), *abrogated on other grounds by Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F. 3d 1142, 1148-49 (Fed. Cir. 2011)). Yet on the other hand, the public interest also supports "eschewing interference with physician choice and preferring a wide array of treatment options." *Kimberly-Clark Worldwide, Inc. v. Tyco Healthcare Grp. LP*, 635 F. Supp 2d. 870, 882 (E.D. Wis. 2009); *see, e.g.*, *Cordis Corp. v. Bos. Sci. Corp.*, No. Civ.A. 03-027-SLR, Civ.A. 03-283-SLR, 2003 WL 22843072, at *1 & *4 n.6 (D. Del. Nov. 21, 2003) (finding that the request for preliminary injunction should be denied because of, *inter alia*, the "acknowledged public interest in a competitive medical device market"), *aff'd*, 99 F. App'x 928, 935 (Fed. Cir. 2004) (explaining that a "strong public interest supports a broad choice of drug-eluting stents" where the

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[22] One of Plaintiffs' primary arguments with respect to the balance of the hardships factor is that HyperBranch assumed a "calculated risk" when it knowingly made, used, sold, offered to sell, and exported the infringing dural sealant products, and that in such circumstances, courts "refuse to weigh" any harm to the infringer. (D.I. 9 at 19; *see also* D.I. 121 at 10) In support, Plaintiffs cite solely to *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983), *abrogated on other grounds by Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F. 3d 1142, 1148-49 (Fed. Cir. 2011). (D.I. 9 at 19; D.I. 121 at 10) The Court does not find the case to be apposite. In *Smith Int'l*, the defendant had made a "clear admission" of infringement and the record therefore "establish[ed] the fact of infringement beyond all question." *Smith*, 718 F.2d at 1579-80 (emphasis omitted); (D.I. 144 at 8 n.5); *see also, e.g.*, *Wavetronix LLC*, 2015 WL 300726, at *9 (explaining that an argument like Plaintiffs' here, "developed in the context of a permanent injunction . . . loses some of its force in the context of a preliminary injunction, where the question of infringement has yet to be conclusively litigated"). For its part, HyperBranch vehemently denies infringement. (*See, e.g.*, Tr. at 122-23; D.I. 144 at 8 n.5)

record contained "evidence that some doctors prefer the [defendant's] stent over the [plaintiff's] stent[,]" even though no published study proved "the superiority of either [plaintiff's] or [defendant's] stent").

HyperBranch proffers the declarations of three neurosurgeons (Dr. Tew, Dr. West and Dr. Hardwidge) who have experience using both products at issue; each expresses a clear preference for the AutoSpray product. (D.I. 94 at 19 (citing D.I. 98-100))[23] Dr. Tew, who has worked as a

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[23] Plaintiffs filed a motion to strike portions of the declarations of these neurosurgeons relating to the alleged "superiority" and "advantages" of the AutoSpray product as compared to DuraSeal, on the grounds that these witnesses were not offered as experts and such testimony is beyond the scope of proper lay opinion. (D.I. 132) Plaintiffs also argue in their reply letter brief that Dr. Hardwidge's declaration should be excluded in its entirety. (D.I. 142) They note that Dr. Hardwidge signed his declaration in the United Kingdom, and the declaration does not comply with 28 U.S.C. § 1746(1)'s requirement that declarations executed outside of the United States must state "I declare (or certify, verify or state) under penalty of perjury *under the laws of the United States of America* that the foregoing is true and correct. Executed on (date)." (D.I. 142 at 2 (emphasis added)) Instead, Dr. Hardwidge's declaration states only that "I swear under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief." (D.I. 100 at 3)

The Court DENIES Plaintiffs' Motion to Strike. The Court agrees with HyperBranch that "[p]hysician preference for the accused product [based on a physician's personal experience with the products at issue] is a highly relevant consideration for the public interest factor of the preliminary injunction analysis[.]" (D.I. 141 at 2); *see also Cordis Corp. v. Boston Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004); *Advanced Cardiovascular Systems, Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 561 (D. Del. 2008). The Court has considered the declarations for that purpose only, focusing on those portions of the relevant declarations that speak to the physicians' personal knowledge of and work with the products. *Cf. Williams v. Mast Biosurgery USA, Inc.*, 644 F. 3d 1312, 1317 (11th Cir. 2011) ("[A] physician may offer lay *opinion* testimony, consistent with [Federal Rule of Evidence] 701, when the opinion is based on his experience as a physician and [is] clearly helpful to an understanding of his decision making process in the situation.") (emphasis in original) (internal quotation marks and citation omitted). And as for Plaintiffs' argument regarding Dr. Hardwidge's non-compliance with Section 1746, other courts have explained that the statute "only requires substantial compliance" and have, in similar circumstances, found "[t]he fact that [the declarant] signed his declaration under penalty of perjury [to be] sufficient[.]" *Ticketreserve, Inc. v. viagogo, Inc.*, 656 F. Supp. 2d 775, 777 n.1 (N.D. Ill. 2009) (*citing Gilmore v. Festo KG*, No. 97 C 5106, 2000 WL 12727, at *2 n.2 (N.D. Ill. Jan. 4, 2000)); *see also* 28 U.S.C. § 1746 (noting that a declaration conforms with the statute's

neurosurgeon for over 50 years and who assisted in bringing DuraSeal to the market, stated that he was an investigator in a clinical trial comparing the two products; he explained that he believes the AutoSpray product to be "a next step forward" in the sealant field, that he "now use[s] [the AutoSpray product] exclusively" and that "[i]t would be a disservice to patients to deprive surgeons of the ability to choose Adherus." (D.I. 98 at ¶¶ 4, 6-8, 10-11, 13) Dr. West, who also participated in a clinical trial comparing the AutoSpray product with DuraSeal over a four-year period, described his negative experiences with DuraSeal; he concluded that "I [] know that DuraSeal does not work to my satisfaction, while I am extremely satisfied with my experience thus far using Adherus." (West Decl. at ¶¶ 4, 5, 8, 11) Dr. Hardwidge, a neurosurgeon for over 23 years, explained that "[i]n my experience, while DuraSeal is an improvement over [fibrin glue], Adherus is better than any sealant I have tried." (Hardwidge Decl. at ¶¶ 4, 6) This is so according to Dr. Hardwidge because "[w]hile several patients [he] treated with [fibrin glue] and DuraSeal experienced subsequent CSF leaks, none of the patients [he has] treated thus far with Adherus has experienced a CSF leak after surgery." (*Id.* at ¶ 8)[24]

Beyond these neurosurgeon declarations, Plaintiffs' own documents (summarized above in Section III.B.4) describe numerous problems [redacted]. Those documents also suggest that the ease of use of the AutoSpray product's applicator helped that product to be seen as more user-friendly than the DuraSeal product.

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requirements if it is "substantially" in the form set out in the statute).

[24] Other Integra documents indicate that certain features of the AutoSpray product, [redacted] would cause neurosurgeons to at least initially prefer the AutoSpray product. (*See, e.g.*, First Pivovar Decl., ex. L at INT00027767, ex. N at 5 & ex. U at 9)

The Court concludes that this factor should weigh in favor of HyperBranch. It does so because: (1) there are only two FDA-approved dural sealant products for cranial procedures that are available in the United States market—Integra's product and HyperBranch's product; (2) the products' use has a real effect on the health of patients who have undergone serious surgical procedures; (3) the record indicates that at least some number of physicians prefer HyperBranch's product to Integra's product (and does not contain much, if any, evidence regarding surgeons who prefer the DuraSeal product over the AutoSpray product); and (4) the record suggests that the DuraSeal product has deficiencies that the AutoSpray product does not suffer from. *See, e.g.*, *Smith & Nephew, Inc. v. Interlace Med., Inc.*, 955 F. Supp. 2d 69, 80 (D. Mass. 2013) (concluding that "[g]iven the importance of optimal patient care, the public interest weighs against granting a permanent injunction" where the defendant presented evidence "showing that at least some doctors consider its product more effective than [plaintiff's] for intrauterine tissue removal"); *Advanced Cardiovascular Systems, Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 561 (D. Del. 2008) (finding the public interest factor to weigh against a permanent injunction where there was a "strong public interest in maintaining diversity in the coronary stent market" and "the record contains evidence of physician preference for [defendant's] stents" in the form of four declarations by cardiologists who all "express[ed] a preference" for the defendant's stents and who "expresse[d] concern for the success of their surgeries should [the defendant's] products be removed from the market"); *cf. Bianco v. Globus Med., Inc.*, Case No. 2:12-CV-00147-WCB, 2014 WL 1049067, at *11 (E.D. Tex. Mar. 17, 2014).

E. Conclusion

Despite assuming *arguendo* that Plaintiffs demonstrated a likelihood of success on the

merits, the Court cannot find that Plaintiffs have met their burden to show that irreparable harm will result absent a preliminary injunction. The remaining two factors also weigh in favor of denial of Plaintiffs' Motion. Therefore, the Court determines that entry of the "drastic and extraordinary remedy" of a preliminary injunction is not warranted here. It thus recommends that the Motion should be denied. *Cf. Hologic, Inc.*, 2016 WL 3143824, at *4-10 (denying motion for preliminary injunction where the likelihood of success on the merits factor weighed in favor of granting the request for one of the two asserted patents but the remaining three factors were neutral).

IV. CONCLUSION

For the reasons set out above, the Court recommends that Plaintiffs' Motion be DENIED.[25]

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website,

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[25] In light of this recommendation, the Court DENIES AS MOOT HyperBranch's motion, (D.I. 134), seeking to strike portions of Plaintiffs' reply brief and supporting materials. *See, e.g., Riverbed Tech., Inc. v. Silver Peak Sys., Inc.*, Civil Action No. 11-484-RGA, 2014 WL 4695765, at *14 & n.16 (D. Del. Sept. 12, 2014); *Cordance Corp. v. Amazon.com, Inc.*, 730 F. Supp. 2d 333, 348 (D. Del. 2010).

located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation.[26] Any such redacted version shall be submitted no later than **August 19, 2016** for review by the Court, along with a motion for redaction that includes a clear, factually-detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: August 12, 2016

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

[26] Accordingly, Plaintiffs' motion seeking leave to file the Declaration of John Jarosz—attached as Exhibit 4 to the First Pascale Declaration—under seal, (D.I. 11), a request that has not been opposed by HyperBranch, is GRANTED.